

# **ADVOCACY IN ARBITRATIONS: CRITICAL ISSUES FACING LITIGATORS IN (BUSINESS) ARBITRATIONS!**

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**Does the ADR clause have an initial or multi-step approach with mediation and then arbitration or litigation? Are those “required” prerequisites to arbitration?**

- What are the Benefits/Detriments to litigators in a multi-step ADR approach? Will earlier settlement be feasible given the “right” neutral?
- There may be a need for compliance with contractual pre-arbitration provision (or condition), i.e. mediation, in order to obtain costs or attorney fees. See Leamon v. Krajkiwicz 107 Cal.App.4th 424, 132 CalRptr2d 362 (2003). And, see the recent decision of Crandall v. Grbic (July 31, 2006, No. 94,846) from the Kansas Appeals Court which held, “summary judgment is appropriate where a party fails to participate in mediation in the face of a mandatory contract provision...” The Crandall decision can be located at <http://www.adrworld.com/si.asp?id=2034>
- What is Med/Arb? A variation of pure mediation/arbitration that could create disclosure, etc. issues? Recent med/arb cases include the following:
  - Where parties entered into agreement for binding mediation with no clearly agreed upon definition of what that meant and later entered into settlement agreement but disagreed as to its implementation, mediator’s determination as to how settlement agreement should be enforced was not enforceable by court under CCP §664.6. Lindsay v. Lewandowski, 43 CalRptr3d 846 (2006).
  - When an arbitrator withdraws from an arbitration proceeding for no stated ethical reason following evidence and argument, and offers to continue mediation efforts but refuses to render an arbitration award, the doctrine of arbitral immunity does not protect the arbitrator from suit since such conduct defeats rather than serves the adjudicatory purpose of arbitration. Morgan Phillips, Inc. v. JAMS/Endispute, No. B183934 (California Appellate Districts, June 20, 2006) <http://www.courtinfo.ca.gov/opinions/documents/B183934.PDF>

- And see the recent decision in The Hess Collection Winery v. California ALRB regarding “mandatory interest arbitration statutes,” e.g. California Labor Code §1164 et seq, wherein a private mediator determined the terms of a contract by which the parties would be bound. This decision has been labeled by some as a “statutory med-arb procedure,” wherein the Court of Appeal ruled “that the procedure does not violate due process or the equal protection clause, nor does it invalidly delegate legislative authority to a private party.” <http://www.courtinfo.ca.gov/opinions/documents/C045405.PDF>
- Other than legislative authorized prelitigation contractual jury waivers they are invalid in California. See Grafton Partners, LP v. Superior Court of Alameda County, 36 Cal. 4th 944, 32 CalRptr3d 5 (2005).

### **Who decides venue questions/objections or location of the arbitration?**

#### **What are the “practical” issues associated with locale?**

- Is there a venue/locale provision in the arbitration clause?
  - Arbitration clauses will often state that the arbitration is to be conducted in a particular locale. For example, the following language clearly states a particular locale: “...by arbitration in Los Angeles, CA, under the Rules of the American Arbitration Association (AAA).” Note, however, that language stating that the arbitration is to be conducted under the laws of a particular State is not the same as language specifying locale.
- What if the locale is not specified in the arbitration clause?
  - When the locale is not specified in the arbitration clause or submission agreement, the claimant will generally request that the hearing be held in a specific locale. If the respondent fails to file an objection to the locale requested by the claimant, the AAA, for example, will confirm its understanding that the locale requested by the claimant is agreeable. AAA Commercial Arbitration Rule 10 specifies the following:

The parties may mutually agree on the locale where the arbitration is to be held. If any party requests that the hearing be held in a specific locale and the other party files no objection thereto within 15 days after notice of the request has been sent to it by the AAA, the locale shall be the one requested. If a party objects to the locale requested by the other party, the AAA shall have the power to determine the locale, and its decision shall be final and binding. (Rules available at [www.adr.org](http://www.adr.org))

- What happens if the respondent objects to claimant’s locale request?
  - When a locale objection is filed, each party is requested to submit written statements regarding its reasons for preferring a specific locale. In preparing their written statements, the parties are asked, for example, by the AAA case manager to address the following issues:
    1. Location of parties and attorneys.
    2. Location of witnesses and documents.
    3. Location of records.
    4. If a construction case, location of site, place or materials and the necessity of an on-site inspection.
    5. Consideration of relative difficulty in traveling and cost to the parties.
    6. Place of performance of contract.
    7. Place of previous court actions.
    8. Location of most appropriate panel.
    9. Any other reasonable arguments that might affect the locale determination.
  
- Who then determines the locale?
  - The determination of locale, based on the parties’ responses to the above issues, is made in the case of AAA arbitrations by a senior member of the Case Management Department. Along with the parties’ responses to the above, the Case Administration Department reviews the Demand for Arbitration, including the applicable arbitration clause, and the answer and counterclaim, if any.
  
- Can the locale determination be appealed?
  - Pursuant to the AAA Rules, the AAA’s determination regarding locale is final and binding. However, if any party believes there are new issues concerning locale that have not been raised, they may bring them to the AAA’s attention. After receiving the comments of the opposing party, the AAA may decline to review its locale determination.
  
- What if the parties only disagree regarding the “place” of the hearing within the same general locale?
  - If the parties disagree on the place of the hearing site (i.e., two places within the same community), the arbitrator may determine the location of the hearing in accordance with the AAA rule governing: “Date, Time, and Place of Hearing.” The word “place” in the rules refers to whether the hearing will be held in an AAA hearing room, attorney’s office, or other facility in the general locale.

- **Relevant venue cases include the following:** Bradley v. Harris Research, 275 F.3<sup>rd</sup> 884 (9<sup>th</sup> Cir. 2001) (modified at 260 FSupp 2<sup>nd</sup> 979) which held that California Business and Professions Code §20040.5 (provides for a California venue for franchise disputes involving out of state franchisor) is preempted by the FAA. See also Bolter v. Orange County Superior Court, 87 Cal.App.4<sup>th</sup> 900, 104 CalRptr2d 888 (2001) with similar facts as Bradley but where the venue clause was argued and found to be unconscionable and severed from the contract. Other preemption cases include Mayo v. Dean Witter Reynolds, 258 FSupp 2<sup>nd</sup> 1097 (ND Cal. 2003), Hedges v. Carrigan, 117 Cal.App.4<sup>th</sup> 578, 11 CalRptr3d 787 (2004).
  - As noted in some of the cases, the impact of the Federal Arbitration Act (FAA) cannot be over-emphasized especially in the area of “venue.” See 9 USC §1 et seq.
  
- California statute on the topic provides as follows:
 

CCP §1282.2. Unless the arbitration agreement otherwise provides, or unless the parties to the arbitration otherwise provide by an agreement which is not contrary to the arbitration agreement as made or as modified by all the parties thereto:

  - (a) (1) The neutral arbitrator shall appoint a time and place for the hearing and cause notice thereof to be served personally or by registered or certified mail on the parties to the arbitration and on the other arbitrators not less than seven days before the hearing. Appearance at the hearing waives the right to notice.
  - ...
  - c) The neutral arbitrator shall preside at the hearing, shall rule on the admission and exclusion of evidence and on questions of hearing procedure and shall exercise all powers relating to the conduct of the hearing. (emphasis added)

### **Will venue influence discovery issues and/or subpoenas?**

- See discussion below in connection with Preliminary Hearings/Discovery and in particular the holding in Dynegy Midstream Services (DMS) v. Trammochem, Division of Transammonia, Inc., 451 F.3d 89 (2nd Cir. 2006)

### **Will venue impact use of “local/foreign” counsel?**

- The California Supreme Court in Birbrower Montalban Condon & Frank PC v. Superior Court, 17 Cal. 4<sup>th</sup> 119, 949 Pac.2d 1 (1998) held that a New York licensed lawyer representing a California client in a California situated arbitration was engaged in the unlawful practice of law. The California Legislature responded with an amended CCP §1282.4—which provides, in part, for an out-of-state-licensed attorney to serve a State Bar Certification on the arbitrator(s), State Bar of California and all other parties/attorneys, etc. This provision currently sunsets January 1, 2007—AB 2482 awaits action in the Senate which would make permanent that law as well as make other changes.
  - Will “non-compliance” by either/both parties result in the award being vacated? And, if operating under the FAA, what is the result?
- Should there be “multi-venues”—especially if there are non-party discovery issues, etc.?

### **Geographical availability of arbitrators’ pool and importance of venue**

- As noted above there are several ramifications in having the appropriate venue. Will, or should, the pool of potential arbitrators be limited/restricted to that particular venue? Should the availability be nation-wide or regional? Should attorneys request a “wide-pool” of arbitrators? Are there any “bias” issues if there is only a narrow pool of available arbitrators?

### **Any other clause enforcement issues?**

- Of course, the normal contract formation related issues may be applicable to the arbitration clause. CCP §1281 provides, “A written agreement to submit to arbitration an existing controversy or a controversy thereafter arising is valid, enforceable and irrevocable, save upon such grounds as exist for the revocation of any contract.” Also see 9 USC §2 and local state statutes on contract formation requirements.
- And, there may be “unconscionability” issues even in a business context. California Civil Code Section 1670.5 provides as follows:
  - (a) If the court as a matter of law finds the contract or any clause of the contract to have been unconscionable at the time it was made the court may refuse to enforce the contract, or it may enforce the remainder of the contract without the unconscionable clause, or it may so limit the application of any unconscionable clause as to avoid any unconscionable result.

(b) When it is claimed or appears to the court that the contract or any clause thereof may be unconscionable the parties shall be afforded a reasonable opportunity to present evidence as to its commercial setting, purpose, and effect to aid the court in making the determination.

- The arbitration agreement must incorporate procedural (oppression/surprise due to unequal bargaining power) and substantive (overly harsh/one-sided result) unconscionability elements to be unenforceable. The Bolter decision cited above has a very good discussion on the procedural and substantive elements of unconscionability. And, then the “severability” of the “suspect” part may be a factor in the result. Does the wording of the “severability” boilerplate impact the result?
- Yet, the February 21, 2006, US Supreme Court decision in Buckeye Check Cashing, Inc. v. Cardegna, 126 S.Ct. 1204, provided definitive guidance on who decides the related issues, i.e. the court or the arbitrator, where it stated, “where a contract contains an arbitration clause, a challenge to the validity of the contract as a whole, and not specifically to the arbitration clause, must go to the arbitrator, regardless of whether the challenge is brought in federal or state court.” And, subsequently a Florida court in Rowe Enterprises LLC v. International Systems & Electronics Corp. (No. 1D06-557) on June 21, 2006, applied the Buckeye guidance. The Buckeye decision is available at <http://www.supremecourtus.gov/opinions/05pdf/04-1264.pdf> Also, see Higgins v. Superior Court, B187818, June 27, 2006, at <http://www.courtinfo.ca.gov/opinions/documents/B187818.PDF>

**Does the arbitrator have the authority to order retention of the “status quo” of the dispute? Does the arbitrator have the authority to preliminarily compel some affirmative action by a party? Is Injunctive/Declaratory relief available or desired?**

- Some clauses explicitly provide a “carve-out” with the court being the forum for certain equitable remedies, e.g. trademark, etc. alleged infringement especially in franchise cases. Other clauses may be silent and merely incorporate applicable arbitral rules.
- Injunctive relief by arbitrators has been recognized in California courts. See Swan Magnetics, Inc. v. Superior Court, 56 CalApp4th 1504, 66 CalRptr2d 541 (1997) where the court (citing and quoting from Advanced Micro Devices, Inc v. Intel Corp., 9 Cal. 4<sup>th</sup> 362, 36 CalRptr2d 581 (1994)) stated that the “arbitrator, unless specifically restrained by the agreement or legal rules, may base [his or her] decision upon broad principles of justice and equity...and make [the] award...according to

what is just and good.” Further at page 546, “arbitrators thus have wide discretion...to fashion a just remedy, including equitable relief that a court may not grant, as long as the remedy is rationally related to the contract and the breach.” And, the decision in Taylor v. Van-Catlin Construction, 130 CalApp4th 1061, 30 CalRptr 690 (2005) provides more recent guidance on the matter. Also, see CCP §1281.8.

- Ultimately counsel needs to compare, and balance, the (purported) arbitrator’s authority in this area with the grounds to overturn an award—see CCP §1286.2.
- AAA Commercial Arbitration Rule 34, “Interim Measures,” specifies the following:
  - (a) The arbitrator may take whatever interim measures he or she deems necessary, including injunctive relief and measures for the protection or conservation of property and disposition of perishable goods.
  - (b) Such interim measures may take the form of an interim award, and the arbitrator may require security for the costs of such measures.
  - (c) A request for interim measures addressed by a party to a judicial authority shall not be deemed incompatible with the agreement to arbitrate or a waiver of the right to arbitrate.
- AAA Commercial Arbitration Rule 43, “Scope of Award,” specifies in part the following:
  - (a) The arbitrator may grant any remedy or relief that the arbitrator deems just and equitable and within the scope of the agreement of the parties, including, but not limited to, specific performance of a contract.
  - (b) In addition to a final award, the arbitrator may make other decisions, including interim, interlocutory, or partial rulings, orders, and awards. In any interim, interlocutory, or partial award, the arbitrator may assess and apportion the fees, expenses, and compensation related to such award as the arbitrator determines is appropriate. ... (emphasis added)
- Advocates sometimes also have to confront an arbitrator’s authority in connection with covenants not to compete. Do arbitrators have the (retained) authority to enforce them?

## **Due-Diligence on arbitrator selection? Party's obligations to disclose relationships, etc?**

- In addition to statutory provisions in California requiring substantial disclosure obligations, see, for example, CCP §1281.85 and applicable California Judicial Council Rules, should the arbitrator issue an order requiring an affirmative disclosure obligation on the parties, witnesses, etc.? After all, who best knows the (past) relationships, who “owns” the underlying dispute (and resultant award) that may be “at risk” if relationships, etc. are not disclosed, etc.?

## **Interviewing of potential arbitrators**

- More and more parties and their attorneys are requesting background information, data on recent attorneys that have appeared before specific arbitrators, particular expertise in a subject matter, etc. This may be an option that the attorneys should seriously consider.

## **Party-Appointed Arbitrators?**

- Neutral versus non-neutral arbitrators—see new Commercial Code of Ethics and specific arbitral rules—are they part of the arbitration agreement? Are old party-appointed clauses controlled by newer/subsequent arbitral rules? Is, or can, a party-appointed arbitrator “really” be neutral? The June 13, 2006, decision in Borst v. Allstate Insurance Co., No. 2004AP2004, 2006 WL 1596123, 2006 WI 70, by the Wisconsin Supreme Court which addresses party-appointed arbitrators and a “presumption” of impartiality/neutrality unless the parties otherwise provide in their arbitration agreement. <http://www.wisbar.org/res/sup/2006/2004ap002004.htm>
- The topic of qualification/disqualification of arbitrators (briefly provided above, is also relevant in the area of party-appointed arbitrators. A good discussion of “evident” impartiality in a non-party appointed situation is the recent 5<sup>th</sup> Circuit case of Positive Software Solutions, Inc. v. New Century Mortgage Corp., 436 F.3d 495 (2006), where an “arbitration award was properly vacated wherein the arbitrator displayed evident partiality through nondisclosure of previous relationship with one party, regardless of whether evident bias was established.”

## **How to remove an arbitrator when all else “fails!”**

- Are there possible ways to “still” remove an arbitrator? Can withdrawing the original arbitration demand and re-filing the demand be an option? What is the arbitral association view on replacing arbitrators?



## What is a Preliminary Hearing?

- Preliminary hearings are generally focused on the procedural, scheduling, etc. matters and conducted before the actual arbitration is commenced—it sets the stage for the arbitration. And, there may be multiple “preliminary hearings,” especially if there is no expedited exchange agreement authorizing direct, albeit not *ex parte* communication, between the attorneys and the arbitrator. The output of the prelim is a scheduling order that establishes the baseline/framework for the covered items. Topics of a prelim should include applicable arbitral rules, any further disclosure issues, discovery (or exchange/production of information) issues, deadline for discovery and non-discovery motions and responses thereto, exchange of witness and exhibit lists (continuing duty to update—no “litigation by ambush”), pre-hearing and post-hearing briefs, applicable “rules of evidence,” form of final award (draft required, reasoned award—separate/independent statement of rationale, “manifest disregard of the law” issues), etc.

Significant issues that can be covered in a preliminary hearing include the following expanded analysis/readings:

- **DISCOVERY.** If no discovery is specified by the applicable rules, can there be any discovery—especially if it is desirable for an arbitration based upon contract? What should be discussed during the preliminary hearing in relationship to discovery? Is having a so-called Large, Complex Case (under for example the AAA rules) desirable, i.e. are there other “controlling” arbitral rules addressing discovery? Do motions for summary judgment have a bearing on whether or not there was discovery? See Schlessinger v. Rosenfeld, 40 Cal.App.4<sup>th</sup> 1096, 47 CalRptr 650 (1995).
  - A current/major issue in discovery is the authority of the arbitrator to compel same against a non-party. Can every non-party be subject to subpoenas for discovery? The recent case of Dynegy Midstream Services (DMS) v. Trammochem, Division of Transammonia, Inc., 451 F.3d 89 (2<sup>nd</sup> Cir. 2006), touches on some issues important on arbitration venue, non-party discovery, etc. And, due to the importance of this subject, an expanded “analysis” of this case is provided hereinafter.

This appeal involved a non-party, DMS, (located in Houston) in an arbitration that ignored a subpoena to produce certain documents and electronic data and subsequently a district court in New York which granted an order to compel compliance by DMS. The 2nd Circuit initially found that it had jurisdiction in that "an order compelling compliance disposes of all issues before the district court...is a final order and immediately

appealable." And the appellate court noted that enforcement of an arbitration subpoena was "a situation closer to that of an administrative agency subpoena" and therefore a district court's order "compelling compliance...disposes of all issues in the case, that order is a final order, and we (the court) have appellate jurisdiction to review it."

The next issue before the court was the asserted lack of personal jurisdiction by the district court over DMS. The court reviewed the language in Section 7 to the FAA including "that the district court in the district in which the arbitrators are sitting may enforce such a summons by compelling attendance or punishing a non-attende for contempt 'in the same manner provided by law for securing the attendance of witnesses or their punishment for neglect or refusal to attend in the courts of the United States'." The court then "turned" to the Federal Rules of Civil Procedure 45 which has geographical limitations on service of process and enforcement, e.g. "service at any place within the district or at any place without the district that is within 100 miles of the place of the deposition, hearing,...production...specified in the subpoena...." The court concluded that "the Federal Rules governing subpoenas to which Section 7 refers do **not** contemplate nationwide service of process or enforcement; instead, both service and enforcement proceedings have clear territorial limitations."

Since the arbitrators were sitting in New York, FAA Section 7 "required that any enforcement action be brought there." The court further found that the language in Section 7 "stands in marked contrast to ...(other) statutes" and held "that FAA Section 7 does **not** authorize nationwide service of process, and the district court therefore erred in asserting personal jurisdiction over DMS."

The court further refused to "craft" a solution advocated by the appellee of a "compromise decision" found in other cases by summarily stating that the FAA confers upon the arbitrators the authority to subpoena documents or witnesses and **not the parties** and that this "gap" as to who is so authorized "**may reflect an intentional choice on the part of Congress, which could well have desired to limit the issuance and enforcement of arbitration subpoenas in order to protect non-parties from having to participate in an arbitration to a greater extent than they would if the dispute had been filed in a court of law. The parties to the arbitration here chose to arbitrate in New York even though the underlying**

**contract and all of the activities giving rise to the arbitration had nothing to do with New York; they could easily have chosen to arbitrate in Texas, where DMS would have been subject to an arbitration subpoena and a Texas district court's enforcement of it."**

- Also see FAA §7; Hay Group, Inc. v. EBS Acquisition Corp., 360 F3d 404 (3rd Cir. 2004)—arbitrator lacks authority to subpoena non-party's production of documents under FAA; and Odfjell ASA v. Celanese AG, 328 F.Supp2d 505 (SDNY, 2004)—non-party not subject to arbitrator's discovery order. But see Festus & Helen Stacy Foundation, Inc. v. Merrill Lynch, Pierce Fenner, & Smith Inc., No. CIV.A. 1:06-CV-0865G, 2006 WL 1490979 (N.D. Ga. May 23, 2006), where the district court held, *inter alia*, that arbitrators had authority to determine scope of discovery for non-parties.
- As noted above and where the FAA is applicable, the filing of the demand and venue become increasingly important and who has the authority to decide venue OR change venue. And, recall venue has a bearing on the unauthorized practice of law issue for out-of-state attorneys. Further, the execution of subpoenas may seemingly become of greater importance. Finally, should there be "multiple" venues or shifting venues?
- And, compare the Dynegy decision with the holding in Sole Resort, S.A. De C.V. v. Allure Resorts Management, LLC, (2<sup>nd</sup> Cir. 2006), where the district court on remand will decide whether the court has personal jurisdiction to vacate an arbitration award.
- The arbitrator has authority to enforce discovery subpoenas (with sanctions for non-compliance) against non-parties in cases involving bodily injury or death (see CCP §1283.05) according to the holding in Berglund v. Arthroscopic & Laser Surgery Center of San Diego, LP, 43 CalRptr3d 456 (2006).
- And, it must be realized that if the attorneys "agree" to discovery "pursuant to the Code," what are the ramifications of such? Does that mean that depositions are for evidence and not for discovery—see CCP §1283.1 and §1283.05(e)? Are there limitations on interrogatories? To what extent can an arbitrator still "manage" the discovery aspects when they are pursuant to the "Code?"

- **AWARD.** While this paper only covers the award topic in the context of “preliminary hearings,” and not as a stand-alone topic for post-hearing vacating/affirming of same (which must also be considered by the reader), the attorney/advocate should be aware that award related issues are usually raised during, intertwined with, at this preliminary hearing stage. The general California arbitration statute is silent on requiring the arbitrator to follow the law. But note the provisions of CCP §1296 relating to construction contracts where the parties for a public construction project may expressly agree that an arbitration award “be supported by law and substantial evidence.” And, can any such award rendered pursuant thereto be vacated if not so supported? The holding in Moncharsh v. Heily, 3 Cal4th 1 (1992), also is crucial in this area.
- However, the grounds to vacate an award must be understood by advocates. See CCP §1286.2 and FAA §10 on the grounds to vacate awards. Specifically Section 1286.2 provides
    - (a) Subject to Section 1286.4, the court shall vacate the award if the court determines any of the following:
      - (1) The award was procured by corruption, fraud or other undue means.
      - (2) There was corruption in any of the arbitrators.
      - (3) The rights of the party were substantially prejudiced by misconduct of a neutral arbitrator.
      - (4) The arbitrators exceeded their powers and the award cannot be corrected without affecting the merits of the decision upon the controversy submitted.
      - (5) The rights of the party were substantially prejudiced by the refusal of the arbitrators to postpone the hearing upon sufficient cause being shown therefor or by the refusal of the arbitrators to hear evidence material to the controversy or by other conduct of the arbitrators contrary to the provisions of this title.
      - (6) An arbitrator making the award either: (A) failed to disclose within the time required for disclosure a ground for disqualification of which the arbitrator was then aware; or (B) was subject to disqualification upon grounds specified in Section 1281.91 but failed upon receipt of timely demand to disqualify himself or herself as required by that provision. However, this subdivision does not apply to arbitration proceedings conducted under a collective bargaining agreement between employers

and employees or between their respective representatives.

(b) Petitions to vacate an arbitration award pursuant to Section 1285 are subject to the provisions of Section 128.7.

- See the decision in Harbert International, LLC v. Hercules Steel Company, 441 F.3d 905 (11<sup>th</sup> Cir. 2006) for a good discussion on manifest disregard of the law standard and the potential impact on attorneys who may “improperly” appeal awards and the use of sanctions against them. And, the recent federal district court decision (reported as of the time of this writing to be on appeal) in Twin Cities Galleries, LLC v. Media Arts Group, Inc., 2006 WL 334908 (D.Minn.2006) where a “court can vacate an award on public policy grounds even when a choice of law provision may otherwise allow an arbitrator to render such a decision.” (Court held, in part, that “...Minnesota established well defined and dominant public policy of protecting its franchisees and the FAA did not preempt anti-waiver provisions of the Minnesota Franchise Act.”)
- And, finally, the landmark California Supreme Court decision in this area, as noted above, is Moncharsh v. Heily, 3 Cal4th 1, 10 CalRptr2d 183 (1992) on the scope of review of an arbitrator’s award, e.g. “errors of law” are generally not a grounds for judicial review.

- **CONFIDENTIALITY OF ARBITRATIONS.** Are arbitrations “confidential?” How can confidentiality of discovery be protected? Who prepares and who should sign a confidentiality order? What if the dispute involves banking or medical records? See, e.g. Health Insurance Portability and Accountability Act (HIPAA) and February 16, 2006 Federal Register notice published by the US Department of Health and Human Services.

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