Several Hooper, Lundy, and Bookman attorneys were in attendance Monday, October 3, 2011, as the Supreme Court heard oral argument in the critically important Medi-Cal rate cases the firm has been handling.

Background

The firm’s cases include California Pharmacists Association v. Douglas, No. 05-1158, in which the firm represents the plaintiff provider organizations and Independent Living Centers of Southern California v. Douglas, No. 09-958, in which the firm represents various providers that have intervened in the matter as plaintiffs. These cases were combined with two other California cases involving Medi-Cal rate issues.

These cases arose from various Medi-Cal rate cuts and limits implemented since 2008. The cuts at issue include the 10% across-the-board rate reduction implemented by California on July 1, 2008, a limitation of Medi-Cal rates for certain inpatient hospital services to 95% of the average rate paid to contracting hospitals effective October 1, 2008, and 5% and 1% cuts to other rates that went into effect March 1, 2009.

The Ninth Circuit Court of Appeals upheld preliminary injunctions, and in one case reversed the lower court’s denial of a preliminary injunction, preventing these cuts from going into effect. The Ninth Circuit found that the state had improperly cut the rates for purely budgetary reasons, had failed to consider the impact of the rate cuts on access and quality, and had failed to consider the relationship of the proposed rates to providers actual costs. The Ninth Circuit also noted that there was evidence that the rate cuts were creating problems with beneficiaries obtaining access to services. The Court concluded that this indicated that the rate cuts would violate Section 30(A) of the Medicaid Act, which requires rates to be consistent with efficiency, economy, and quality of care, and sufficient to ensure that beneficiaries have equal access to services.

The Ninth Circuit ruled that Medi-Cal beneficiaries and providers could bring a claim for relief under the Supremacy Clause of the United States Constitution, which in essence provides that federal law shall be the supreme law of the land. State law that is in conflict with federal law is preempted by the federal law and is invalid.

California asked the United States Supreme Court to review these cases. The Court agreed to hear only the following issue:

Whether Medicaid recipients and providers may maintain a cause of action under the Supremacy Clause to enforce Section 30(A) by asserting that the provision preempts a state law that may reduce payments to providers.

The Court declined to accept for review the question of

In This Issue

- Supreme Court Hears Medi-Cal Rate Arguments
- Physician Supervision Requirements
whether the Ninth Circuit properly interpreted and applied Section 30(A).

**Importance of Issue**

The resolution of this issue is of vital importance to Medicaid recipients and providers. The ability of Medicaid recipients and providers to sue states where the state cuts Medicaid rates so much that the rates violate federal law would be placed in serious jeopardy if the state prevails. States are facing significant fiscal pressures, and Medicaid is a large component of most states’ budgets. In the absence of recipient and provider litigation to ensure at least minimally adequate rates, or the threat of such litigation, states will likely feel free to balance their budgets by cutting Medicaid payment rates. This will inevitably lead to a lack of access for beneficiaries to necessary and critical services.

Further, as Medicaid patients cannot find access to physicians and other practitioners who can no longer afford to care for them, the patients will end up in hospital emergency rooms, a much more costly site of care. Further, the already crowded emergency rooms will become overcrowded, and waiting times for services will increase. The financial well being of many hospitals will then be placed in jeopardy, as hospitals will see an influx of Medicaid patients while their payments are also being cut. This downward spiral could very well lead to hospital closures. The closure of a hospital affects the availability of health care services to everyone, not just Medicaid recipients.

Finally, the outcome of this case will likely have significant implications for health care reform. Health care reform under the Affordable Care Act depends on the enrollment of tens of millions of Americans in Medicaid in 2014. If California prevails and states starve their Medicaid program of necessary funding, these new beneficiaries will obtain coverage that may be largely illusory as they will not be able to find participating providers. This would place the success of health care reform in serious jeopardy.

**The Supreme Court Hearing**

We are cautiously optimistic from the comments of the Justices at the hearing Monday that the ability of beneficiaries and providers to sue states when their Medicaid rates are so inadequate that they violate the federal Medicaid Act will be preserved.

The discussion at the Court was lively, with each Justice except Justice Thomas peppering the lawyers for both sides with provocative questions. The questioning provided insight into the Justices’ views and the potential outcome.

Several of the Justices appeared to support a broad right to sue states under the Supremacy Clause to pursue a claim that state law violates federal law and is therefore pre-empted and invalid. These Justices, including the Court’s newest additions Justices Sotomayor and Kagan, were troubled by the state’s argument that the Supremacy Clause should be treated differently than virtually all other Constitutional provisions, which the courts have found create a private right of action to enforce their provisions.

Most of the Justices were very concerned with the fact that California had implemented the Medi-Cal rate cuts prior to even submitting them to the federal government for approval, let alone obtaining that approval, and continuing to implement the cuts even after they were disapproved by CMS. These Justices appeared to understand clearly that if beneficiaries and providers could not sue, the states could feel free to act in violation of federal law in order to balance their budgets without fear of significant consequences.

Justice Roberts seemed to be the most hostile to the position of the beneficiaries and providers. His view appeared to be that allowing beneficiaries and providers to sue under the Supremacy Clause to contend that a state rate cut violates Section 30(A) would effectively undo more than two decades of Supreme Court decisions that have substantially limited the rights of private parties to bring a claim under a federal statute. Justice Roberts appears to believe that a statute must expressly confer a right to sue for a private party to be able to bring a claim for its enforcement, and he did not see any such language in Section 30(A).

Justice Breyer’s questioning provided a window into a possible middle ground that could garner at least five votes. This would be a ruling that would allow beneficiaries and providers to sue states under the Supremacy Clause, or perhaps more generally under the courts’ equitable powers, to seek an injunction prohibiting states from implementing rate cuts until CMS has had an opportunity to review the cuts and approve or disapprove. Under this approach, the avenue available to challenge a rate cut that has been approved by CMS might be a suit against CMS under the Administrative Procedures Act, rather than a suit against the state under the Supremacy Clause.

We expect that the Court will issue its decision during the first quarter of 2012. This decision will certainly
have enormous consequences for those who depend on state Medicaid programs for their health care, providers who open their doors to the poor, and ultimately our entire health care delivery system.

For additional information, please contact Lloyd Bookman or Patric Hooper in Los Angeles at 310.551.8111; or Mark Reagan or Craig Cannizzo in San Francisco at 415.875.8500.

More Changes Ahead to Physician Supervision Requirements for Hospital Outpatient Therapeutic Services

By Patricia H. Wirth

It has been hard for hospitals to stay abreast of all of the changes the Centers for Medicare & Medicaid Services (“CMS”) has made to the physician supervision requirements for outpatient therapeutic services over the past few years, and it is not going to get any easier. In the 2012 Medicare outpatient prospective payment system (“OPPS”) proposed rule, CMS has proposed establishing an independent advisory process to review outpatient therapeutic services and to make recommendations to CMS to assign some services to higher or lower levels of supervision. While the changes CMS is proposing may result in less intensive supervision levels and more flexibility for some services, it may prove difficult for hospitals to implement the new supervision levels as CMS announces them every six months. To understand the proposed changes, it is helpful to begin by looking at the evolution of the supervision requirements.

Direct Supervision Requirement for Outpatient Therapeutic Services

Medicare Part B covers therapeutic services furnished to hospital outpatients that are provided “incident to” the services of a physician in the treatment of his or her patients. Therapeutic services generally include all services or procedures that are not considered diagnostic in nature, such as clinic services, observation services and emergency room services.

When the hospital OPPS began in 2000, CMS adopted physician supervision policies as a condition of payment. CMS specified that direct supervision was required for most outpatient therapeutic services pro-
vided in hospitals and in provider-based departments ("PBDs") of hospitals. Direct supervision meant that the physician had to be physically on the premises and immediately available to furnish assistance and direction throughout the procedure. CMS emphasized that the direct supervision requirement applied to services provided at off-campus PBDs, but said it assumed the direct supervision requirement was met when the outpatient services were provided on campus.

In light of CMS’ “assumed” satisfaction of the direct supervision requirement for outpatient services provided on campus, many hospitals thought that it was unnecessary to designate or document specific physicians as the supervising physicians. Hospitals typically deemed their emergency department physicians to be functioning as the supervising physicians for all outpatient therapeutic services performed on campus.

The 2009 Final Rule’s “Clarification”

In the years after the initial OPPS regulations, CMS received many questions from hospitals that led CMS to believe hospitals were providing only general supervision or no supervision at all for outpatient therapeutic services provided on hospital premises. This prompted CMS in the preamble to the 2009 OPPS final rule to “clarify” that the supervising physician for services furnished in the hospital and in all PBDs of the hospital must be present in the department and immediately available when outpatient therapeutic services were being provided. That meant hospitals could not rely on their emergency department physicians to supervise outpatient therapeutic services performed on campus, since the emergency department physicians were not physically present in the departments where the services were being provided.

The 2010 Final Rule Relaxed the Definition of Direct Supervision

In the 2010 OPPS final rule, CMS relaxed its direct supervision requirement for therapeutic outpatient services provided on hospital campuses by allowing the supervising physician to be physically present anywhere on the same campus. However, the supervising physician still had to be immediately available, which CMS defined to mean that the physician was physically present, interruptible and able to furnish assistance and direction throughout the performance of the service.

CMS gave hospitals further flexibility by allowing physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives and licensed clinical social workers to supervise outpatient therapeutic services if these non-physician practitioners personally furnished the services and the services were within the respective practitioner’s scope of practice under State law and the privileges granted by their hospital (clinical psychologists were already allowed to supervise outpatient therapeutic services).

The 2011 Final Rule Deleted the Boundary Requirement

The 2011 OPPS final rule further redefined direct supervision to remove all requirements that the supervising physician be on the same campus or in the department of an off-campus PBD. While CMS removed the boundary requirement, it continued to require that the supervising physician be immediately available. CMS also established a new category of outpatient therapeutic services, “nonsurgical extended duration therapeutic services,” that have a substantial monitoring component. These services include services for observation, IV hydration and patient-controlled anesthesia pumps. Direct supervision is required for the initiation of these services; however, once the physician has determined the patient is stable, the service can continue under general supervision. (General supervision means the service is furnished under the overall direction and control of the physician, but the physician’s physical presence is not required.) The point of transition from direct to general supervision must be documented in the medical record.

The 2012 Proposed Rule’s Process to Establish New Supervision Requirements for Many Services

In the recent 2012 OPPS proposed rule, CMS has now proposed that an independent advisory entity, the existing Advisory Panel on Ambulatory Payment Classification Groups (the "APC Panel"), evaluate individual outpatient therapeutic services and make recom-
mendations to CMS concerning the appropriate level of physician supervision for each of the services. The APC Panel may recommend that a particular service be assigned to a less intensive (general) level of supervision or to a more intensive (personal) level of supervision. As proposed, “personal” supervision would mean that a physician has to be in the room during the service or procedure.

CMS proposes that a “subregulatory” process that is not subject to formal notice and comment rulemaking be used for its final decisions on supervision requirements. According to CMS, this would allow for a more flexible and frequent process and allow CMS to take action more quickly to revise a supervision requirement if necessary. However, prior to finalizing any supervision requirements, CMS’ proposed decisions would be posted on the OPPS Web site with a period for public comment. Any new supervision requirements would be effective the following January or July. In addition, hospitals could request reevaluation of CMS’ decisions, but they would have to provide significant justifications to support such a request (such as new clinical evidence, new technology or new techniques in how patient care is provided).

When evaluating the appropriate level of supervision for a particular service, the APC Panel would take into consideration any available clinical evidence and any known impacts of supervision on the quality of care. The APC Panel would also consider the varied environments in which the particular service may be delivered. The Panel will further assess the likelihood that the supervising physician would reassess the patient and change the treatment or give guidance to the practitioner providing the service. In making this assessment, CMS proposes that the APC Panel consider: (1) the complexity of the service, (2) the patient’s acuity, (3) the probability that an unexpected or adverse patient event would occur, and (4) the likelihood that rapid clinical changes would occur during the service.

The APC Panel would be able to select which services it evaluates, but CMS could also request that the APC Panel review certain services. In addition, CMS plans to solicit services for evaluation from hospitals.

CMS has clarified that the direct supervision requirement also applies to critical access hospitals (“CAHs”), but issued a notice instructing its contractors temporarily not to enforce the requirement with respect to CAHs. The nonenforcement notice was expanded to include small rural hospitals with 100 or fewer beds. While the new independent review process is being established, CMS expects it will extend the notice of nonenforcement for these hospitals through December 31, 2012.

**Conclusion**

CMS continues to state that the most appropriate level of supervision for most hospital outpatient therapeutic services is direct supervision, that is, the physician must be immediately available (present and interruptible) to furnish assistance and direction throughout the performance of a therapeutic service or procedure, but does not have to be present in the room where the service or procedure is being performed. The proposed advisory process may result in more appropriate supervision levels for particular services which may enhance the quality of patient care. The new supervision levels may also allow for more flexibility and reduce costs when supervision levels are lowered.

However, the revised supervision levels may also prove to be of more form than substance. If a department performs several different outpatient services that have a mix of general and direct supervision levels, the hospital will need to provide the more intensive direct level of supervision for the department as a whole, even though some services require less supervision. While it is not known yet what impact new supervision requirements will have on hospitals, it is clear that when the process begins, hospitals will have to monitor the OPPS Web site frequently to keep up to date with the new requirements and then carefully track what supervision levels apply to which services.

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| October | 19 | CHA EMTALA Webinar  
Steve Lipton presents an EMTALA update. |
|---------|----|------------------------------------------------------------------|
|         | 20 | G2 Intelligence 29th Annual National Lab Institute, Arlington, VA  
Patric Hooper co-presents and participates on a panel titled  
*What Should Keep You Up at Night: Lowest Lab Pricing May BE Closer Than You Think.* |
|         | 26-28 | Progressive Healthcare Conferences - Stark  
Charles Oppenheim presents a Stark Update webinar. |
|         | 31 | Managed Care Leaders Summit, New Orleans  
Glenn Solomon speaks on managed care issues. |
|         |    | HLB Webinar -- ACO Final Regulations  
Lloyd Bookman and Charles Oppenheim present a Comprehensive overview of the final ACO regulations. |
| December | 1 | Managed Care in California: Current Battles and Future Solutions  
LACBA – Healthcare Law Section  
Charles Oppenheim and David Hatch -- Program Planning Committee  
Amanda Hayes will present on providers perspective in the program Developing Trends in Managed Care Litigation (Perspectives from Health Plan and Provider Counsel) |
| December | 6 | CHA Behavioral Health Symposium  
Steve Lipton presents *EMTALA & Behavioral Health Care – Rethinking the Rules of Engagement* |
| May     | 11 | SCAHRM 32nd Annual Conference  
Steve Lipton and Jodi Berlin present a Regulatory Update. |

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