On October 26, 2012, the California Department of Public Health (DPH) announced proposed regulations regarding administrative penalties for general acute care, acute psychiatric and specialty hospitals. If finalized, these regulations will permit DPH to assess higher penalties for violations that constitute immediate jeopardy and assess penalties for violations that do not constitute immediate jeopardy.

Pursuant to California Health and Safety Code section 1280.1, prior to the effective date of regulations governing administrative penalties, DPH may assess penalties of up to $50,000 for a first immediate jeopardy violation in three years, $75,000 for a second immediate jeopardy violation and $100,000 for a third immediate jeopardy violation. Pursuant to California Health and Safety Code section 1280.3, after the effective date of regulations, DPH may assess: (1) penalties of up to $75,000 for a first immediate jeopardy violation in three years, $100,000 for a second immediate jeopardy violation and $125,000 for a third immediate jeopardy violation and (2) penalties of up to $25,000 for non-immediate jeopardy violations. DPH has issued these proposed rules to assess the maximum penalties against hospitals for violations.

Health and Safety Code section 1280.3 mandated DPH to develop criteria for the assessment of penalties, including, but not limited to: (1) The patient's physical and mental condition; (2) The probability and severity of the risk that the violation presents to the patient; (3) The actual financial harm to patients, if any; (4) The nature, scope, and severity of the violation; (5) The facility's history of compliance with related state and federal statutes and regulations; (6) Factors beyond the facility's control that restrict the facility's ability to comply with this chapter or the rules and regulations promulgated thereunder; (7) The demonstrated willfulness of the violation; and (8) The extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring. DPH is required to comply with this statutory mandate.

The proposed regulations advance the adoption of new sections 70951 through 70960 and sections 71701 through 71703 of Title 22 of the California Code of Regulations. These proposed regulations address the assessment of penalties for deficiencies, i.e., a facility's failure to comply with any law relating to the operation or maintenance of a hospital as a requirement under licensure under the Health and Safety Code or Division 5 of Title 22 of the California Code of Regulations. Separate provisions address the assessment of penalties for violations of the hospital fair pricing policies requirements at Health and Safety Code sections 127400, et seq.

Assessment of Penalties for Deficiencies

DPH proposes to borrow heavily from the federal nursing home citation system to assess penalties against hospitals. Specifically, the regulations propose to assign an initial penalty pursuant to a severity and extent of noncompliance grid that is similar to the scope and severity grid created by the Centers for Medicare and Medicaid Services to assess the seriousness of deficiencies prior to assessing civil monetary penalties in long-term care facilities. DPH then proposes to adjust the initial penalty amount based on various adjustment factors. The assessed penalties would be subject to the maximum penalties defined in Health and Safety Code section 1280.3.
Scope of Regulations

The proposed regulations would apply only to the assessment of administrative penalties under Health and Safety Code section 1280.3. The proposed regulations specifically exclude minor violations, which are defined as violations of law that the DPH determines has only a minimal relationship to the health or safety of hospital patients. The proposed regulations also exclude penalties assessed by DPH under laws other than Health and Safety Code section 1280.3, such as those for whistleblower protections, medical information breaches, adverse event reporting and transfer protocols and policies. The proposed regulations also do not apply to any settlement of an enforcement action.

The proposed regulations would only apply to incidents occurring on or after the effective date of the regulations. However, DPH proposes to consider compliance history prior to the effective date of the regulations in assessing penalties.

Assessment of Penalties

Central to the proposed regulations is a matrix designed to determine an initial penalty for a deficiency by selecting a penalty percentage from a range provided in the matrix cell that corresponds with various severity of harm levels and corresponding percentages of non-compliance:

<table>
<thead>
<tr>
<th>Extent of Noncompliance</th>
<th>Minimal</th>
<th>Moderate</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity Level 6 – Immediate jeopardy to patient health or safety - Death</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Severity Level 5 – Immediate jeopardy to patient health or safety – Serious injury</td>
<td>60%</td>
<td>70%</td>
<td>80%</td>
</tr>
<tr>
<td>Severity Level 4 – Immediate jeopardy to patient health or safety – Likely to cause serious injury or death</td>
<td>40%</td>
<td>50%</td>
<td>60%</td>
</tr>
<tr>
<td>Severity Level 3 – Actual harm that is not immediate jeopardy</td>
<td>60%</td>
<td>80%</td>
<td>100%</td>
</tr>
<tr>
<td>Severity Level 2 – No actual harm but with potential for more than minimal harm, not immediate jeopardy</td>
<td>20%</td>
<td>35%</td>
<td>50%</td>
</tr>
<tr>
<td>Severity Level 1 – No actual harm but with potential for no more than minimal harm</td>
<td>Minor violation – No penalty</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DPH proposes that it will consider the patient’s physical and mental condition and the probability and severity of risk that the violation presents to patients in assigning a severity level for the violation.

The three levels of non-compliance are:

- **Minimal** – The action or inaction deviates from the requirement, but it complies to some extent, although not all of its important provisions are complied with.
- **Moderate** – The action or inaction deviates from the requirement, but it complies to some extent, although not all of its important provisions are complied with.
- **Major** – The action or inaction deviates from the requirement to such an extent that the requirement is completely ignored and none of its provisions are complied with, or the function of the requirement is rendered ineffective because some of its provisions are not complied with.

An immediate jeopardy penalty is considered a first penalty if the date of the violation is over three years from the date of a previous immediate jeopardy penalty. DPH proposes to consider previous immediate jeopardy penalties assessed prior to the rulemaking, but within three years of a subsequent immediate jeopardy, when determining whether the subsequent immediate jeopardy is a first, second or third deficiency.

Penalty Adjustment Factors

Once DPH calculates the initial penalty, it proposes to apply a first set of adjustment factors to calculate the “base penalty.” DPH then proposes to apply a second set of adjustment factors to calculate the final penalty.
Initial Penalty Adjustment Factors

Initial penalties may be adjusted upward from five to 10 percent based on the patient's physical impairment resulting from a violation. The initial penalty may also be adjusted upward by one percent if the violation caused financial harm to the patient. The initial penalty may be reduced by 5 percent for factors beyond the hospital's control that restrict the hospital's ability to comply with licensure requirements, if the hospital developed and maintained disaster and emergency programs that were appropriately implemented during a disaster. This reduction for factors beyond the hospital's control appears to be limited to natural disasters and emergencies. The initial penalty may also be increased by 10 percent if the deficiency was the result of a willful violation.

Base Penalty Adjustment Factors

Immediate Correction of the Violation

The base penalty may be adjusted downward by 20 percent, if:

• The hospital identifies and immediately corrects the noncompliance, subject to certain requirements;
• The noncompliance does not constitute immediate jeopardy or result in patient death;
• The hospital met mandatory reporting requirements before it was identified by the department; and
• A penalty was not imposed for a repeat deficiency for which the hospital received a penalty reduction within a 12 month period of the current violation.

Compliance History with State and Federal Laws

The base penalty may be adjusted downward by 5 percent if the hospital's inspections over the previous three years noted no state or federal deficiencies that resulted in patient harm or immediate jeopardy.

The base penalty may be adjusted upward by five percent if the hospital had three or more repeat deficiencies that pose a risk of minimal harm to the patient within the last three years of inspections.

Penalties for Violations of Hospital Fair Pricing Policy Requirements

The initial penalty for violations of hospital fair pricing policy requirements are based on three categories of deficiency:

• Major -- If it appears a requirement has been completely ignored, or none of its provisions complied with, the initial penalty is $2,000.
• Moderate -- If the action or inaction deviates from, but com-
plies to some extent with the requirement, the initial penalty is $1,000.
• Minimal -- If the hospital complies with the requirement nearly as it was intended, there is no administrative penalty.

However, initial fair pricing policy penalties may adjusted upward by 5 percent if the violation caused financial harm to the patient, and 10 percent if the violation is found to be willful.

The base penalty may be adjusted downward by 20 percent if the hospital immediately corrected the violation and all the following criteria are met:

• The hospital corrected the noncompliance before identified by DPH;
• The hospital completes corrective action within 10 days of identification; and
• The penalty was not imposed for a repeat deficiency that previously received a penalty reduction in the last 12 months.

The base penalty will be increased by 10 percent if the hospital has had one or more related violations in the past three years.

Small and Rural Hospitals

Small and rural hospitals that are assessed penalties under Section 1280.3 may request reduced penalties, as well as payment extensions based on financial hardship, reduction in the penalty if extended payment plan would cause extreme financial hardship.

The notice of proposed rulemaking and the proposed regulation may be viewed at:

http://www.cdph.ca.gov/services/DPOPP/reg/Pages/DPH-09-012AdministrativePenalties-GeneralAcuteCareHospitals,AcutePsychiatricHospitals,andSpecialHospitals.aspx

Written comments on these proposed regulations are due on December 10, 2012. Hooper, Lundy & Bookman, PC is collecting information from hospital providers related to this important rulemaking package. If you would like to share your experiences with the current state survey system or have other comments with respect to this proposed rulemaking, please contact Felicia Y Sze at 415-875-8503 or fsze@health-law.com.

If you would like to discuss these proposed regulations further or would like assistance preparing comments, please contact: Hope Levy-Biehl or Jodi Berlin in Los Angeles at 310.551.8111; Mark Reagan, Steven Lipton or Felicia Y Sze in San Francisco at 415.875.8500; or Mark Johnson in San Diego at 619.744.7300.
Veteran Transactional Attorney Sandi Krul Joins HLB

Hooper, Lundy & Bookman is pleased to announce that Sandi Krul has joined the firm’s transactional department in Los Angeles.

Ms. Krul specializes in real estate transactions, including leasing, as well as managing acquisition closings and dispositions. She has represented a wide variety of organizations, including nonprofit corporations, publicly traded organizations and governmental entities. As with all HLB attorneys, Ms. Krul also brings with her knowledge of the regulatory aspects of transactions from a health law perspective.

“We are pleased to add Sandi’s experience and expertise in our firm,” said Managing Partner Robert Lundy. “As the number and complexity of real estate transactions we handle continues to grow, Sandi’s expertise is very valuable.”

A graduate of Loyola Law School, Ms. Krul was admitted to the California Bar in 1995. She also has a Graduate Certificate in Health & Hospital Law from Seton Hall Law School.

Ms. Krul may be reached at skrul@health-law.com or 310.551.8137.

FCC Task Force Outlines Barriers and Proposed Solutions to Mobile Health Technology

By 2017, mobile health (mHealth), wireless health and e-care solutions should be routinely available as part of best practices for healthcare, according to a Federal Communications Commission (FCC) task force report released September 24. The report was issued by the mHealth Task Force, which was convened in June 2012 by FCC Chair Julius Genachowski. Members of the task force were selected for their wireless healthcare technology expertise.

Barriers to Adoption and Innovation

The task force identified several major barriers to adoption and innovation of wireless technology in healthcare, including:

- Reimbursement regulations and policies that do not provide incentives for mHealth solutions.
- A lack of secure messaging between health information systems.
- Lack of access to fixed and mobile broadband coverage for providers and patients, especially in rural areas.
- Future bandwidth constraints brought on by increased usage and data intensive medical applications.
- Patient safety, privacy, and interoperability issues between healthcare solutions.
- A broadband adoption gap for both fixed and mobile broadband services.

Recommendations for Overcoming Barriers

In order to overcome the identified barriers, the task force recommended that the FCC continue to play a leadership role in advancing the adoption of mHealth technology. Noting that the position of FCC Healthcare director is currently open, the task force recommended that the position be filled and that the director should serve as a liaison with other federal agencies. The task force suggested that regular stakeholder meetings be scheduled. Task force members offered to serve as outreach for attracting appropriate candidates. As a leader, the FCC should also improve educational outreach activities, develop a healthcare website and establish the mHealth task force as a formal interagency external working group, according to the task force.

The task force also recommended the following additional steps:

- Federal agencies should increase collaboration to promote innovation, protect patient safety, and avoid regulatory duplication. Federal agencies identified by the task force included agencies within the Department of Health and Human Servic-

HLB Briefs

HLB is pleased to announce that the firm’s Los Angeles, San Francisco and San Diego offices have all been recognized as Tier 1 law firms for 2012-2013 by Best Law Firms.
es, the Veterans Administration, the National Science Foundation, the National Institutes of Health, the Department of Defense, the Department of Commerce, the U.S. Department of Agriculture, and the National Institute of Standards and Technology.

- The FCC should build on existing programs and link programs when possible to expand broadband healthcare access. Included here is a recommendation to reform the Rural Health Care Program.
- The FCC should continue its efforts to increase capacity, reliability, interoperability and safety of mHealth technologies.
- The industry should support continued investment, innovation, and job creation in the mobile health sector.

“We see growing involvement from the FCC in the promotion of broadband and mobile communications among health care providers,” said HLB Attorney Paul Smith. “We will continue to monitor the FCC’s activities, particularly as they promote innovations that raise privacy, security and patient safety concerns.”

For additional information, please contact Paul Smith or Stephen Phillips in San Francisco at 415.875.8500; Hope Levy-Biehl in Los Angeles at 310.551.8111; Jennifer Hansen in San Diego at 619.744.7300, or Robert Roth in Washington, D.C., at 202.580.7500.

CMS Agrees to Clarify Medicare’s Maintenance Coverage Standards in Proposed Settlement Agreement

By Felicia Sze and David Vernon

On October 16, 2012, the Secretary of the U.S. Department of Health and Human Services (the Secretary) and the other parties to Jimmo v. Sebelius (Jimmo) (D.Vt. 5:11-cv-17) submitted a proposed settlement agreement to the District Court of Vermont for its approval. The plaintiffs in the Jimmo case challenged the Secretary’s alleged denial of skilled services on the basis that beneficiaries were unlikely to improve from the care (i.e., the “improvement standard”). The plaintiffs alleged that pursuant to this “improvement standard,” the Secretary had covertly adopted a policy to deny coverage where the beneficiary was not improving, was receiving “maintenance services only,” had “plateaued,” was “chronic,” or was “medically stable.” Pursuant to the terms of the settlement and upon approval by the court, the Secretary will clarify that Medicare will cover skilled nursing and therapy services that are provided to maintain or slow further deterioration in a beneficiary’s current condition, regardless of whether the patient is expected to improve.

Case Background

The Center for Medicare Advocacy filed a class action suit against Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, in the federal district court of Vermont on January 18, 2011, to prevent the Secretary’s alleged application of the “improvement standard” to deny Medicare coverage for skilled nursing and outpatient therapy services. Among the plaintiffs were six Medicare beneficiaries who needed skilled care, such as skilled nursing facility care, home health services or outpatient therapy services, but allegedly were unable to access these services due to Medicare’s “improvement standard.” Also among the plaintiffs were seven organizational plaintiffs including the National Committee to Preserve Social Security and Medicare, the National Multiple Sclerosis Society, the Parkinson’s Action Network, the Paralyzed Veterans of America, the American Academy of Physical Medicine and Rehabilitation, the Alzheimer’s Association, and United Cerebral Palsy.

The plaintiffs alleged that lower-level decision-makers had enforced an “improvement standard,” based on certain informal policy statements. The plaintiffs further alleged that the application of the “improvement standard” resulted in the termination, reduction, or denial of coverage for thousands of very sick Medicare beneficiaries annually. As a result, the alleged Improvement Standard purportedly impacted beneficiaries with chronic conditions who were unlikely to ever improve, but for whom skilled care could potentially help maintain their functional ability and slow their disease’s progress.

The plaintiffs asserted that Medicare statutes and regulations precluded the implementation of an “improvement standard” with respect to coverage of skilled services. Specifically, the complaint alleged that the Medicare Act and implementing regulations provide for coverage of services that are “reasonable and necessary” “for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.”

The complaint asserted that the application of the “improvement standard” violated the Medicare Act and its implementing regulations with respect to the medical necessity requirement, violated the procedural requirements of the Medicare Act, violated the Administrative Procedure Act by failing to comply with the requirements of notice-and-comment rulemaking, violated the Freedom of Information Act by failing to be published in the Federal Register, and violated the Due Process Clause of the Constitution.
The Secretary filed a motion to dismiss the plaintiffs’ amended complaint on the basis that the court lacked subject matter jurisdiction and on the basis that the plaintiffs had failed to state a claim upon which relief may be granted. Notably, the Secretary disputed the existence of an “improvement standard,” in part because its own regulations and policies “effectively prohibit the use of a so-called ‘Improvement Standard[,]” The court denied the motion to dismiss on this ground, finding that the evidence of coverage denials to the plaintiffs was sufficient to demonstrate the plausibility of the application of the “improvement standard.”

After the court’s order on the motion to dismiss, the Secretary requested to stay the proceedings in an effort to settle the suit to avoid discovery. After 10 months of settlement discussions, the plaintiffs and the Secretary presented a proposed settlement agreement to the court for its approval. External sources suggest that the court is likely to approve the settlement agreement in early 2013.

Settlement Terms

Pursuant to the proposed settlement agreement, the Secretary has agreed on behalf of the Centers for Medicare and Medicaid Services (CMS) to: amend the Medicare Manuals to clarify maintenance coverage standards; create an educational campaign to ensure people in charge of coverage decisions can apply the laws and regulations correctly; perform accountability measures to ensure correct coverage decisions; and re-review denials for certain members of the class.

Amendment of Medicare Manuals. CMS will revise portions of the Medicare Benefit Policy Manual to clarify the coverage standards for skilled nursing facility (SNF), home health (HH), and outpatient therapy (OPT) benefits when a patient has no restoration or improvement potential but when that patient needs skilled SNF, HH, or OPT services. The revisions will indicate that coverage decisions will not turn on the beneficiary’s potential for improvement from the therapy or skilled nursing services, but rather on the beneficiary’s need for the skilled care. The Secretary agreed to finalize and issue revised manual provisions within one year of the court’s approval of the proposed settlement agreement.

The changes will clarify for both therapy services under the SNF, HH, and OPT benefits and nursing services under the SNF and HH benefits that a maintenance program will be covered when the specialized judgment, knowledge, and skills of a qualified therapist or qualified nurse are necessary. However, the manual will clarify that where an individualized assessment does not demonstrate a necessity for such skilled care, for example, where the maintenance program can be safely and effectively accomplished by the patient or with the assistance of non-therapists or unskilled caregivers, then such maintenance services will not be covered by Medicare.

Moreover, the manual revisions will clarify that skilled care is necessary: 1) when the particular patient’s special medical complications require the skills of a qualified therapist or qualified nurse to perform the service that would otherwise be considered non-skilled; or 2) when the needed procedures are of such complexity that the skills of a qualified therapist or nurse are required to perform them.

The Secretary will also revise the Medicare Benefit Policy Manual to clarify that a claim for services at an inpatient rehabilitation facility may never be denied for the following reasons: (1) because a patient could not be expected to achieve complete independence in the domain of self-care or (2) because a patient could not be expected to return to his or her prior level of functioning.

Educational Campaign. CMS will engage in a nationwide educational campaign which will communicate the SNF, HH, and OPT maintenance coverage standards to Medicare contractors, adjudicators, and providers and suppliers via written materials and interactive forums that include, national calls and open door forums. The Secretary agreed to carry out the educational campaign within one year of the court’s approval of the settlement agreement.

Accountability Measures. CMS will put in place accountability measures requiring it to monitor coverage decisions by: 1) randomly sampling coverage decisions to ensure compliance with the laws and regulations; 2) directing review where the sampling indicates errors have been made; 3) addressing entities where patterns of incorrect decisions can be attributed; and 4) meeting on a bi-annual basis with Plaintiff’s counsel to discuss the sampling process for a total of five meetings.

Re-Review Process. Finally, CMS will offer a re-review process for certain qualifying class members. These qualifying class members are defined as Medicare beneficiaries who: 1) received skilled nursing or therapy services in a SNF, HH, or OPT setting; 2) received a denial of coverage because of a lack of improvement potential and the denial became final and non-appealable on or after January 18, 2011, and before the end of the educational campaign; and 3) seeks Medicare coverage on his or her own behalf. Explicitly excluded from the class are: 1) providers or suppliers of Medicare services and Medicaid state agencies, 2) any otherwise qualifying class members whose services were covered or paid by “any third party payer or insurer or Medicare,” with a limited Medicaid exception, and 3) any otherwise qualifying class members who received denials that included any basis for denial other than the alleged “improvement standard.”

Class members who are eligible for re-review of claim denials will be put into two groups. Group 1 will include class members whose Medicare claim denials became final and non-appealable between January 18, 2011 and the date the court approves the
settlement agreement. Group 2 will include class members whose Medicare claim denial became final and non-appealable between the day after the Approval Date through the end of the educational campaign. Group 1 class members must identify themselves to CMS no later than six months after the end of the educational campaign and Group 2 class members must identify themselves to CMS no later than twelve months after the end of the educational campaign. Where the re-review process confirms an error, the agency will reimburse for that care.

Impact of the Settlement Agreement

If approved by the court, the settlement agreement will impact the rights of Medicare beneficiaries and provide certainty with regard to coverage determinations for skilled SNF, HH, and OPT maintenance services. As increasing numbers of Medicare beneficiaries suffer from multiple chronic conditions, this proposed settlement agreement will clarify that Medicare will cover reasonable and necessary services for maintenance services, including skilled nursing and therapy services, for these beneficiaries.

Upon approval, Medicare beneficiaries, and not providers, have the sole right to re-review of claim denials. We recommend that providers consider assisting their patients who may fall in the class to request re-review of their claim denials where these claims have not been paid by a third party payer, insurer or Medicare. Because a redetermination appeal must be made within 120 days, we believe that denials from as early as September 20, 2010 may still qualify for re-review. Moreover, we recommend that providers consider appealing any claim denials they receive based on the “improvement standard” to preserve their rights.

For further information or assistance, please contact Mark Reagan, Scott Kiepen, Felicia Sze or David Vernon in San Francisco at 415.875.8500; John Hellow in Los Angeles at 310.551.8111; Mark Johnson in San Diego at 619.744.7300; or Robert Roth in Washington, D.C. at 202.580-7700.

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1 42 U.S.C. § 1395y(a)(1)(A); see also 42 C.F.R. §§ 409.32(c), 409.44(a), (b)(1), (b)(3)(iii), (c)(2).

2 The court granted in part the Secretary’s motion to dismiss for lack of subject matter jurisdiction with regard to one individual plaintiff on the basis that she had not presented her claims to the Secretary and to one organizational plaintiff on the basis that it did not meet the legal test for associational standing.
The California Hospital Association has released a newly revised edition of
**EMTALA — A Guide to Patient Anti-Dumping Laws.**

Authored by Hooper, Lundy & Bookman Attorney, Steven Lipton, the 8th edition includes the following changes:

- A new chapter describing the complexities of applying EMTALA and California’s mental health laws (LPS) to treating emergency psychiatric patients
- Updating the position of CMS on asking emergency patients for financial/insurance information and aggressive debt collection activities
- Changes to California law allowing emergency services to be provided by non-physician practitioners in specified situations
- Guidance on how to respond and prepare for QIO/HSAG reviews and hearings on EMTALA cases
- Update regarding EMTALA obligation waivers during disasters and public health emergencies

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