PEDIATRIC BUSINESS AND HEALTHCARE DELIVERY SERIES

Today's Top Compliance Issues for Children's Hospitals
Fourth of a Six-Part Series

July 26, 2012

ECG MANAGEMENT CONSULTANTS

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Agenda

I. Top Compliance Concerns
- Perspectives from Children's Hospital Los Angeles
- Perspectives from Children's National Medical Center
- Perspectives from Foley & Lardner

II. Differences in Compensation FMV Opinions

III. Conclusions

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I. Top Compliance Concerns

Perspectives from Children's Hospital Los Angeles

- Reimbursement concerns.
- Privacy and safety concerns.
- Social media concerns.
- Research.
- Healthcare reform.

Reimbursement Concerns

- Payor mix.
  - Small Medicare population.
    - Typically only end-stage renal disease (ESRD) on dialysis.
  - Large Medicaid (Medi-Cal) population.
    - Patiently awaiting Medi-Cal RAC audits.
  - California Children's Services (CCS) population.
  - Significant charity care.
- Payment changes.
  - Move to Medi-Cal DRG.

Privacy and Security Concerns

- Concerns regarding consent and authorization for minors.
  - Emancipated minors, self-sufficient minors, carve-outs by California law.
- California requires breach reporting with 5 days.
  - California requirement are more strict than federal requirements.
- Required breach reporting to parents within 5 days.
  - Requires additional work to notify parents and translate into spoken language.

Social Media Concerns

- Cell phone use by patients, family, and staff.
- Photo, video policies.
- Posting on Facebook and other social media sites.
- iPads, Skyping, texting.
- Celebrity visits and events.

Other Compliance Concerns

- Research.
  - Minors can consent and authorize on their own for certain research and care.
  - Assent by the child.
  - Record retention.
  - Biorepository.
- Healthcare reform concerns.

Perspectives from Children's National Medical Center

Top-of-Mind Compliance Issues

- Current concerns include:
  - PHI encryption (together with bring your own device [BYOD] issues).
  - Social media.
  - Billing (physician documentation/up coding/payor audits).
  - Conflicts of interest.
- What is the big picture?

PHI Encryption

- ***Any*** breach of PHI affecting 500 or more individual patient records must be reported to the Office of Civil Rights (OCR) and made public via newspaper or Web site.
  - This creates significant risk to an organization.
    - Use of both technical means and policy development to comply.
    - Proofpoint, Inc. (and other automated e-mail encryption services).
  - The BYOD trend compounds compliance issues.

PHI Encryption *(continued)*

- Policies should be put into place whereby:
  - Outbound e-mail containing PHI must be encrypted.
  - These e-mails are filtered and scanned for multiple key elements that will trigger automatic encryption.
    - A few examples of such triggers are CMS Common Procedure Coding System codes, CMS disease codes, date-of-birth terms, drug names, routes and dosage, Social Security Administration terms and expressions, and SSN.
  - So, if you must have PHI on your laptop or thumb drive, ***the device must be encrypted, and you should always have less than 500 patient names or other identifying pieces of information.***

Social Media

- Why have a Social Media Policy?
  - Opportunity to connect with patients, the community, and the greater public, as well as across health systems.
  - Social media is not going away.
- What should your Social Media Policy provide?
  - Recognize that social media tools are ubiquitous and that patients, visitors, and employees will access them and "talk about" you.
  - Explicitly pull in and make applicable other policies of your institution: HIPAA, local confidentiality laws, workplace harassment/violence policies, and other employee conduct policies.

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Social Media *(continued)*

- The positive side:

Concussion Assessment & Response (CARE): Sport Version

Jason Mihalik, Ph.D., CAT(C), ATC, and Gerard A. Gioia, Ph.D.

Purpose: Provides tools for athletic trainers, team physicians, and other qualified healthcare professionals to assess the likelihood of a concussion and respond quickly and appropriately.

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Billing

- This is an age-old compliance issue.
- There is a constant need to (re)educate physicians and other practitioners.
- Increased audit risks by Medicaid and other payors should be addressed.
- Simple mistakes can easily cost millions in payback, not to mention exposure to fines and penalties.

Billing *(continued)*

- Basic teaching physician documentation requirements:
  - The physician must document that he or she performed the service or was present during key or critical portions of the service. The physician's personal participation in the management of the patient must be documented, and the combined entries of the resident and teaching physician must support the level of service billed.
  - In supervising procedures performed by residents, the teaching physician must be present during all key portions of the procedure or immediately available to him or her. (Found in CMS Claims Processing Manual 100.1.1.)

Conflicts of Interest

- New rules, greater scrutiny.
- **NIH standards for research**:
  - The new rules related to research take effect August 24, 2012.
  - The purpose of the regulations is to promote objectivity in research by establishing standards to ensure that NIH-funded research will be free from bias resulting from investor financial conflict of interest (FCOI).
  - A research organization will now be required to post its FCOI policy on its publicly accessible Web site and also be required to disclose (whether online or in response to written requests for information) any identified FCOIs of senior/key personnel of the NIH-funded research project.
  - Further information regarding the revised regulations may be found at *http://grants.nih.gov/grants/policy/coi/coi_faqs.htm.*

Conflicts of Interest *(continued)*

- The threshold at which investigators must report significant financial interests was lowered from $10,000 to $5,000.
  - A financial interest counts as “significant” if it involves the investigator, his/her spouse, or his/her dependent children and is related to any of the investigator’s institutional responsibilities (not just his/her research).
- Additional requirements are that the institution must report the name of the company in which there is a conflict, the value of the interest, why it is a conflict, and key elements of how the institution is managing the conflict.

What Is the Big Picture?

- The goal of compliance in any organization is to help it achieve ***"High Performance With High Integrity."***[1]
- This is an excellent formulation, because it ties the "bottom line" in a narrow financial sense to the broader bottom line of a sustainable organization.

[1] Ben W. Heineman, Jr. (former CLO of GE Healthcare), Harvard Business Press, 2008.

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Achieving "High Performance With High Integrity"

"When I gave performance-with-integrity presentations to GE business leaders, I leaned heavily on a slide that had only two bullets:

- Create the systems and processes.
- Create the culture."

Source: *"High Performance with High Integrity,"* Ben W. Heineman, Jr., Harvard Business Press, 2008.

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Perspectives from Foley & Lardner

Top Five Compliance Issues Facing Children's Hospitals

#1 Thinking Children's Hospitals Are Untouchable

#2 Treatment of Medicaid Overpayments

#3 False Claims Act (FCA) and Whistle-Blowers

#4 Anti-Referral Laws

#5 Provision of Substandard Care

Issue #1: Thinking Children's Hospitals Are Untouchable

- Many believe that the government turns a blind eye to children's hospitals when investigating or prosecuting healthcare fraud and abuse claims.
- Despite the compassionate work performed and services provided, compliance issues exist within these hospitals.
- The most significant compliance risk, therefore, is assuming that children's hospitals are untouchable.

Issue #2: Treatment of Medicaid Overpayments

- PPACA Section 6402 – 60-Day Refund Rule (March 23, 2010) (in effect now for Medicare, Medicaid, Medicaid Managed Care, and Medicare Advantage).
- Providers, suppliers, and plans living under the statute.
- CMS's Proposed Rule on Medicare Overpayments (February 13, 2012).
- Various states rolling out their own compliance requirements for Medicaid.
  - Warning! States are not mirroring Medicare's proposed rule!

Issue #2: Treatment of Medicaid Overpayments *(continued)*

1. **Civil Monetary Penalties Law**

- Failing to report and return known overpayment within 60 days or when cost report due (such failure is also subject to potential FCA liability).
  - SSA Sec. 1128A(a); 42 USC 1320a–a(a) (N.B. does show in online SSA/USC).

2. **FCA "Obligation"**

- PPACA § 6402(a): Express duty to refund and report Medicare and Medicaid overpayments.
- By ***the later*** of 60 days after overpayment is "identified" ***or*** the date cost report is due.
- Failure to report and return is an "obligation" for the purpose of FCA.
  - SSA Sec. 1128J(d); 42 USC 1320a-7k(d).

3. **(Medicare and) Medicaid Program Exclusion**
   - SSA Sec. 1128A.; 42 USC §1320a-7a and SSA Sec. 1902(a); 42 USC 1396a(a).

Issue #2: Treatment of Medicaid Overpayments *(continued)*

- CMS Proposed Rule: blockbuster: **10-year look-back *(the "outer limit of the FCA statute of limitations")***.
- CMS also proposes to revise the reopening period to 10 years.
- CMS thinks it provides "a reasonable period that [providers and suppliers] can close their books and not have ongoing liability associated with an overpayment."
- *NOTE:* Many state Medicaid programs have no explicit look-back period. Defer to statutes of limitation?

Issue #3: FCA and Whistle-Blowers

- The lack of significant volumes of Medicare reimbursement needs to be acknowledged.
- Results in:
  - Decreased OIG attention.
  - Lack of effective guidance (e.g., CMS manuals, MedLearn, regulatory preambles, Advisory Opinions).
  - Dispersed billing and regulatory requirements (state by state).

Issue #3: FCA and Whistle-Blowers *(continued)*

- Enhancements to the FCA since 2009: FERA and PPACA.
  - Multiple phases at chipping away at defenses.
  - Improperly retained overpayment is an "obligation" (see Issue #2).
  - FERA eliminates requirement that claim be presented to the U.S. (as had been read into 31 USC 3729(a)(1)).
  - PPACA weakens public disclosure bar (only if disclosed in a federal criminal, civil, or administrative hearing, or a federal report, hearing, audit, or investigation).
  - Expansion of the definition of an original source (eliminates the direct knowledge requirement).
  - Kickbacks triggering FCA.

Issue #3: FCA and Whistle-Blowers *(continued)*

- Driscoll Children's Hospital in Texas agreed to pay $14.5 million to settle claims of providing false information to the Texas Department of State Health Services (TDSHS), which led to overpayments by Medicaid.
- The hospital allegedly filed false expense reports to the TDSHS, reported inflated figures on charity work, and participated in possible violations of state and federal anti-kickback statutes (AKSs).

Issue #3: FCA and Whistle-Blowers *(continued)*

- In 2008, the owner of a Wisconsin company that provided prenatal and child care coordination services was sentenced to 5 years in prison and ordered to pay more than $320,000 in restitution for billing Medicaid for services never rendered or for non-covered services.
- In 2011, Treehouse Pediatric Clinic of Texas entered into a settlement agreement for $1.4 million with the U.S. to resolve allegations that the clinic presented claims for payment with TRICARE for services provided to autistic children by noncertified, unlicensed behavioral therapists.

Issue #4: Anti-Referral Laws

- Multiple sets of laws to consider.
  - Federal AKS.
  - State AKSs.
  - Federal Stark law (physician self-referral law).
  - State "Baby Stark" laws.
  - State "fee splitting" prohibitions.

Issue #4: Anti-Referral Laws *(continued)*

- Why is AKS a concern?
  - New emphasis on physician alignment strategies.
  - Children's hospitals' network relationships with traditional acute care health systems.
  - New risk arrangements in the market.
  - Lack of "sensitivity" to the issue in C-suites at children's hospitals.

Issue #4: Anti-Referral Laws *(continued)*

- What is the role of Stark?
- Medicare covers not just the elderly.
  - Persons with disabilities.
  - ESRD.
- Thus, there are Medicare-covered services in children's hospitals – and Stark Law exceptions must be met, or Medicare cannot be billed.
- Note application of PPACA 6402 (60-Day Refund Rule).

Issue #4: Anti-Referral Laws *(continued)*

- Medicaid and Stark.
  - Commonly misunderstood.
  - Medicaid reimbursement systems are very different from Medicare – each state has different definitions, payment rules, bundling, etc.
  - Section 13624 of OBRA 1993 added SSA 1903(s): extended Stark to Medicaid.
  - Bars federal financial participation for state expenditures for services furnished to an individual based on a prohibited referral if it would be prohibited by Medicare.

Issue #4: Anti-Referral Laws *(continued)*

- HCFA Proposed Rule – *Federal Register*, Vol. 63, 1659–1704, January 9, 1998.
- How the referral prohibition and sanctions affect Medicaid providers:

  "… we do not believe these rules and sanctions apply to physicians and providers when the referral involves Medicaid services. The first part of section 1903(s) prohibits the Secretary from paying FFP to a State for designated health services furnished on the basis of a referral that would result in a denial of payment under Medicare if Medicare covered the services in the same way as the State plan. This part of the provision is strictly an FFP provision. It imposes a requirement on the Secretary to review a Medicaid claim, as if it were under Medicare, and deny FFP if a referral would result in the denial of payment under Medicare. Section 1903(s) does not, for the most part, make the provisions in section 1877 that govern the actions of Medicare physicians and providers of designated health services apply directly to Medicaid physicians and providers. As such, these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services. A State may pay for these services, but cannot receive FFP for them. However, States are free to establish their own sanctions for situations in which physicians refer to related entities."

Issue #4: Anti-Referral Laws *(continued)*

- Impact of Stark to Medicaid:
  - State cannot get FFP for a service if referral would be prohibited by Medicare.
  - Reporting requirements (if implemented) will apply to Medicaid, though HCFA contemplated reporting to the states (i.e., reporting all physicians with ownership, investment, and compensation arrangements).
- State regulations may incorporate Stark by reference.

Issue #4: Anti-Referral Laws *(continued)*

- McAllen Hospitals, a hospital group based in Texas, agreed to pay the U.S. $27.5 million to settle claims that it violated the FCA, AKS, and Stark law between 1999 and 2006 by paying illegal compensation to doctors to induce them to refer patients to hospitals within the group. These payments were disguised through a series of sham contracts, including medical directorships and lease agreements.
- The government also implicated Edinburg Children's Hospital, an affiliate of McAllen Hospitals, in this investigation:
  - Beginning in 2005, the hospital group paid Harish Koolwal, M.D., as if he was the Medical Director, but the children's hospital did not open until 2006.
  - The Department of Justice (DOJ) alleged that Dr. Koolwal was one of seven doctors within the system to receive "bogus" job titles, lease agreements, and other payouts in exchange for referring patients to hospitals within the group.

Issue #5: Provision of Substandard Care

- The OIG has the authority to exclude any entity from participation in federal healthcare programs if the entity provides unnecessary or substandard items or services.
  - Neither knowledge nor intent is required for exclusion.
- This also has a significant PR risk (the "*New York Times* test").
- Recommendations:
  - Hospitals should continually measure their performance against comprehensive standards.
  - Hospitals should develop their own quality-of-care protocols and implement mechanisms for evaluating compliance with these protocols.
  - Hospitals must monitor the quality of medical services by overseeing the credentialing and peer review of their medical staffs.

Issue #5: Provision of Substandard Care
(continued)

- CPC Southwind, a children's psychiatric hospital in Oklahoma, paid $750,000 to the U.S. to resolve allegations that it defrauded Medicaid by treating children in an unsafe and harmful environment and then billing Medicaid for the services.
- The complaint alleged that CPC charged the government for inpatient care of children and adolescents "who were subjected to unreasonable risks of physical and mental harm." Further, it was improper for CPC to admit government-insured patients into such an environment and to bill the government for the care of these patients.
- CPC closed after reaching the settlement.

Issue #5: Provision of Substandard Care
(continued)

- The DOJ accused Holland-Glen, a residential treatment nursing facility for respirator-dependent children, of defrauding the U.S. by providing substandard care and failing to provide necessary nursing care. The complaint alleged that Holland-Glen failed to: (1) respond to respiratory alarms, (2) comply with physician orders for pulse oximeters, (3) prevent severe bed sores, and (4) administer medications properly.
- Alleged Holland-Glen's services substantially departed from generally accepted professional standards of care, thereby exposing patients to significant risk and, in some cases, to actual harm.
- Moreover, although it promised to provide skilled nursing services to the residents of the facility, Holland-Glen never applied for and did not possess any license from the Commonwealth of Pennsylvania to operate such a facility. Holland-Glen had a license to operate only as a community group home for mentally challenged persons.

II. Differences in Compensation FMV Opinions

Navigating Uncertainty

An absence of relevant and reliable market data makes it difficult to know what level of physician compensation is "excessive."

- When hospitals seek to employ a rare pediatric subspecialty, they often rely heavily on market data to determine how much to pay.
- In many instances, there is not a sufficient amount of relevant data.
- Such a lack of data creates multiple problems:
  - While hospitals can accept the reality of a money-losing practice to support a larger mission, they seek to minimize these losses.
  - In other cases, hospitals are often willing to pay substantial salaries, but are concerned that these amounts exceed FMV.

The fact that a physician earned a certain amount in a previous setting does necessarily mean that amount is FMV. Moreover, the historical pay may not be sufficient. Enter the valuation consultant.

The Risk-Tolerant Environment

Consider the following hypothetical scenario:
Two hospitals compete to employ a physician; both may be willing to pay as much as the appraiser will say is FMV, but there are multiple valuation opinions.

- Hospital A and Hospital B both wish to hire the same physician.
- In private practice, this physician reports earning $250,000 per year under a net income model (documentation is provided).
- The physician will likely generate $500,000 in hospital income from ancillary and hospital services.
  - Hospital A is equipped to absorb 50% of this business.
  - Hospital B is equipped to absorb 100% of this business.
- Absent regulatory restrictions, Hospital B would be willing to pay more than Hospital A, but both are limited to paying FMV.

Hospitals A and B instruct their appraiser to tell them the maximum amount that can be paid within FMV.

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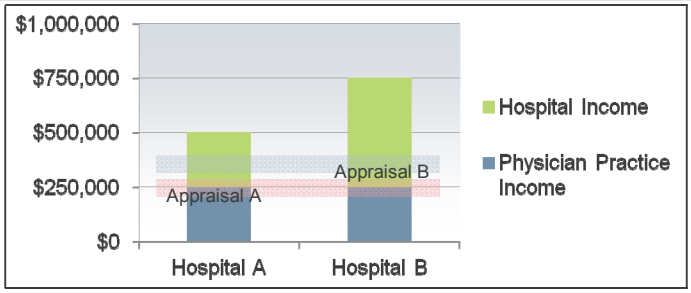
Setting the Stage for Opinion Shopping

Both parties are willing to pay even more than the upper end of the valuation, but they are limited to paying what the report states as FMV. In all likelihood, the hospital with the higher opinion will "win" the transaction.



The cost of not getting the deal done is immediate and relatively certain, whereas the cost of potential FMV risk may appear low, especially in light of the fact that both appraisers present similar qualifications and experience. So, why do they differ?

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Reconciling the Discrepancies

Valuators can differ in many aspects of a compensation opinion.

Source of Difference	Comments
Survey Selection	There are multiple national, regional, and specialty-specific surveys.
Specialties	If applicable, another similar specialty may be deemed sufficiently comparable.
National vs. Regional	Valuators differ on the relative applicability of regional vs. national data.
Valuation Metrics	Common metrics include compensation, compensation per WRVU, and compensation-to-collections ratios. One or more metrics may be deemed relevant to a given arrangement.
Data Adjustments	Benchmark adjustments may include survey data lag, region, practice setting, etc.
Valuation Approaches	A market approach is the most common method, but not the only one.
Range Selection	Appraisers may differ in how qualitative factors influence the selection of a relevant percentile.
Weighting	Variations exist in how benchmarks, metrics, and approaches are weighted.

Valuators should explain why a data source or approach was used and another not used, lest the opinion be tainted by advocacy, rendering it unreliable.

Special Considerations for Rare Subspecialties

Explaining such nuances to a physician with a higher offer is unlikely to produce the desired outcome. As a result, it may be beneficial to ensure that the valuation opinion has considered all relevant facts and circumstances.

- While appraisers should not be encouraged to change an opinion to meet a predetermined business objective, there may be other relevant data that has not yet been considered.
- Compensation for certain pediatric subspecialists often cannot be determined by a direct evaluation of benchmarks.
- If the subspecialty is not reported or underreported in the surveys, benchmark adjustments may be warranted using data that is sufficiently reported.
- Market data should be added or removed, depending on applicability.
- Other valuation approaches may be used (i.e., cost and market approaches).

If reported benchmarks are insufficient, they should not be exclusively relied upon.

Special Considerations for Rare Subspecialties
(continued)

If the valuator does not have a high level of familiarity with pediatric practices, it may be useful to review the basis for inclusion or exclusion of data sources.

- The relevance of the survey data being used should be considered, given the practice setting.
- Survey data may still be useful for determining market compensation levels, even if the subspecialty is not adequately reported.
  - The relative relationship between reported adult and pediatric subspecialties may be used to develop market compensation rates.
  - Compensation surveys and data sources with pertinent information may have been inadvertently excluded from the analysis.
- Other valuation methods may be, and often are, appropriate (i.e., cost and income approaches).

Valuation opinions are most reliable when they consider all available and relevant information. Hospitals often have superior knowledge of data sources and should ask the valuator if such data should be considered.

Parting Thoughts

When a valuation opinion is the "gating factor" for getting a deal done, there should be a great deal of scrutiny on the reliability of the report. At the same time, excessive conservatism may create a competitive disadvantage.

- Ascertain the valuation consultant's understanding of and experience with the business of pediatric healthcare.
- Ensure the opinion states the basis for use and exclusion of data sources, methods, and approaches in the report.
- Consider the economic realities of a practice when determining compensation.
- Beware of reliance on "rules of thumb" as opposed to valuation methodologies using reliable data sources.

If two opinions differ, it does not necessarily mean one of them is wrong, but it also does not mean that either of them is right.

III. Conclusions

- Compliance remains an important element in hospital operations, and it is important that upper management appreciate that fact, as well.
- While children's hospitals have perhaps not had the highest-profile cases, that does not mean the exposure does not exist.
- As is the case in healthcare generally, devoting resources to compliance yields a better organization – one which avoids the kind of trouble that can be very costly in terms of both dollars and reputation.

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Questions & Answers

To submit a question for any of our presenters, type it into the Question and Answer pane at the right of your screen at any time.

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We hope you will join us for future programs in the Pediatric Business and Healthcare Delivery Series, which will feature the following topics:

- Information technology.
- Research and teaching.
- Subspecialty physician practice – managing teaching, research, and clinical missions in the presence of shortages.