Emerging Issues In Healthcare Law for ASCs

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EEOC

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Current Legislative Efforts
ASC Quality & Access Act of 2013
(H.R. 2500/S 1137)

Requires the Centers for Medicare & Medicaid Services (CMS) to use the Hospital Market Basket Index as the update factor when determining the update for payments for services performed in ambulatory surgery centers (ASCs). This act would change the ASC update factor from the Consumer Price Index–Urban Consumers (CPI-U) to the more accurate Hospital Market Basket Index.
Currently, ASCs’ payments are updated based on the CPI-U, which does not appropriately measure the costs of an ASC. CPI-U measures changes in the costs of ALL consumer goods, however, it is not related to the costs of health care of ASCs.

Hospital Out Patient Department (HOPD) payments are updated based on the hospital market basket, which specifically measures changes in health care costs. This more accurately reflects the increased costs that outpatient facilities face.

Since consumer prices have inflated more slowly than medical costs, the gap in ASC and HOPD reimbursement rates has widened over time. In the end, the risk is that ASCs will be forced to merge with hospitals, significantly increasing costs to the Medicare program.
ASC Quality & Access Act

Over the last 10 years, ASC reimbursement rates have declined in comparison to HOPD reimbursement rates and are now on average 58% of what an HOPD receives for a similar procedure.

This is an unsustainable trend that must be stopped in order for ASCs to remain a viable alternative to the higher cost HOPD setting.
ASC Quality & Access Act

Other Key Issues

Add an ASC representative to the Advisory Panel on Hospital Outpatient Payment.
- Currently nineteen (19) members, not one (1) from the ASC community.

Require Transparency in Determining the ASC Procedure List.
- CMS would be required to disclose which of the criteria triggers the exclusion of a procedure from the ASC approved list and prohibits CMS to exclude procedures reported with unlisted codes.
- Adding procedures that can be performed safely in the ASC setting saves Medicare and its beneficiaries money.
ASCs currently save the Medicare system $2.6 billion a year and if just half of the eligible procedures were moved to the ASC setting from HOPDs, it would save the system another $2.5 billion.

ASCs offer a lower infection rate, state of the art technologies, significant savings and a higher commitment to quality of care.

ASC procedures take an average of 31.8 fewer minutes than hospital procedures, with a 25 percent average time reduction between the surgery locations. Outcomes in hospitals and surgery centers were comparable, but surgical costs were between $400 and $1,000 lower for ASC cases.

ASCA Advocacy Efforts

The Ambulatory Surgery Center Association (ASCA) continues to reach out to CMS policymakers to educate them on how ASCs can help even more Medicare beneficiaries, including the additional procedures that ASCs could safely and effectively perform. Consider helping and supporting the ASCA’s efforts by:

- Writing a letter to your member of Congress
  [www.ascassociation.org/TakeAction](http://www.ascassociation.org/TakeAction)

- Attending Capitol Fly-In
  [www.ascaassociation.org/2014CapitolFlyIn](http://www.ascaassociation.org/2014CapitolFlyIn)

- Hosting a Facility Tour (for member of Congress)
  [www.ascaassociation.org/FacilityTour](http://www.ascaassociation.org/FacilityTour)
Colorectal Cancer

• According to the American Cancer Society, deaths from colorectal cancer have been declining for more than two decades, mostly because of screenings, including colonoscopies and other tests.

• The United States Preventive Services Task Force guidelines call for individuals of average risk of colon cancer between the ages of 50 and 75 to be screened, but only about half in the US are screened as recommended.
Colorectal Cancer Screening Act

Need for Legislation

Preventive care services allow medical problems to be discovered and treated earlier, saving the US health care system, insurers and patients money and, more importantly, saving lives. Colorectal cancer is a preventable disease but continues to kill 50,000 Americans each year.

The CDC estimates that if all precancerous polyps were identified and removed before becoming cancerous, the number of new colorectal cancer cases could be reduced by 76 to 90 percent.
The “Removing Barriers to Colorectal Cancer Screening Act” works to correct an oversight in current law that requires Medicare beneficiaries to cover the cost of their copayment/coinsurance for a screening colonoscopy if a polyp is discovered and removed during the procedure.
Under current law, Medicare waives copayment/coinsurance and deductibles for colonoscopy screenings. When a polyp is discovered and removed, however, the procedure is reclassified as therapeutic for Medicare billing purposes and patients are required to pay the coinsurance.
H.R. 1070/S. 2348 would eliminate unexpected costs for Medicare beneficiaries when a polyp is discovered and removed, ensuring that unexpected copays do not deter a patient from having the screening performed.

By eliminating financial barriers, this legislation would attain higher screening rates and reduce the incidence of colorectal cancer.
Congress passed the HITECH Act of 2009 to incentivize Medicare providers to adopt and use EHR systems.

Eligible professionals (EP) who see the majority of their patients in ASCs may not be able to meet the meaningful use requirements mandated by HITECH due to the fact that there are no EHRs certified for the ASC setting.

The meaningful use program states that in order to avoid payment penalties beginning as early as 2015, all EPs must conduct fifty percent (50%) or more of their Medicare patient encounters in a setting with a certified EHR technology (CEHRT).
Unfortunately, ASCs were not eligible for HITECH funds to develop EHR systems, and no certified EHR is currently available for ASC encounters. Thus, a process has not been set up to certify an EHR for the ASC setting.

Current legislation may dissuade physicians from using ASCs—often a lower-cost option—because patient encounters in the ASC setting currently count toward the physicians’ total encounters but cannot meet “meaningful use” requirements.
Electronic Health Records Improvement Act

- Most physicians that provide services in ASCs also provide additional services at other facilities or might even provide services at another ASC.

- EPs that provide services in more than one location must still meet the threshold of 50 percent of their patient encounters being documented in a certified EHR.

- This requirement can be met by seeing patients at one or many locations, including Ambulatory Surgical Centers.
EHR proposes a short-term exemption to the Health Information Technology for Economic and Clinical Health Act (HITECH) that would allow physicians to provide care in ASCs for three years following its enactment without having the cases they perform there factored into the “meaningful use” requirements.

This exemption will allow ASCs the time they need to develop standards for EHR that meet the unique needs of the ASC setting.
Electronic Health Records Improvement Act

Allowing physicians to perform procedures in ASCs without fear of being penalized encourages them to continue to choose the lowest cost setting of care.

Providing this short-term reprieve will give the ASC community time to explore ways to develop criteria for EHR systems that can be certified for this unique setting, which would benefit both physicians and patients. Please encourage all members of the US House of Representatives to offer their support to H.R. 1331.
The Health and Human Services Office of the Inspector General (OIG) recently issued a Special Fraud Alert on laboratory payments to referring physicians.

Specifically, the alert is concerned with Specimen Processing Arrangements and Registry Arrangements, which OIG believes pose substantial risks of fraud and abuse under the federal anti-kickback statute. (AKS)
OIG is focusing on two trends which have the potential of posing a "substantial risk of fraud and abuse" under the federal Anti-Kickback Statute ("AKS").

1. Payments to physicians to collect, process and package patients’ blood specimens ("Specimen Processing Arrangements").

2. Payments to physicians for the performance of certain duties, typically involving data collection and reporting services, in connection with the clinical lab’s operation of a registry database ("Registry Payments").
According to the alert, a “Specimen Processing Arrangement” is an arrangement where a physician is paid by a clinical laboratory to collect, process and package patients’ blood specimens. The alert explains that these arrangements typically involve a laboratory paying a physician for certain specified duties, such as collecting and centrifuging blood specimens, maintaining the specimens at a particular temperature and specimen packaging to prevent damage in transport.

Payments in Specimen Processing Arrangements are typically structured as a “per specimen” or a “per patient-encounter” payment.

The OIG is concerned that physicians are receiving double payment these services. Double payment occurs when a physician is paid by a laboratory and is paid by a third party such as Medicare through a receipt of a specimen collection fee or a bundled payment for service.
Registry Arrangements

The alert describes a “Registry Arrangement” as an arrangement under which a clinical laboratory creates, coordinates or maintains databases purportedly to collect information on patients who have undergone or may undergo certain tests performed by the laboratory.

The purpose of these registries is generally the promotion of clinical research and knowledge-sharing for the treatment of these patients. Typically, the tests involved in Registry Arrangements are specialized and expensive.

OIG’s concern is that participation in Registry Arrangements may influence a physician to order medically unnecessary tests and that the referral will be made to the lab participating in the Registry Arrangements, in lieu of referring to a clinically superior lab.
The alert lists certain characteristics of Specimen Processing Arrangements and Registry Arrangements that may provide evidence of improper intent under AKS, including:

- Payment exceeding fair market value for services actually rendered by the physician or party receiving the payment;

- Payments for services for which a physician is separately compensated from another source, such as Medicare;

- Payment made directly to the ordering physician rather than to the physician’s group practice, which may have incurred the cost of collecting and processing the specimen;
Evidence of Improper Intent (cont.)

• Payment is made on a per specimen, per test, per patient or other basis that takes into account the volume or value of the referral
  – (Note: Medicare reimburses only one specimen collection fee even if more than one specimen is drawn);

• Payments for services/ tests that may be duplicative or that are otherwise not reasonable and necessary.
  – Payment may not be offered on the condition that the physician orders a specific volume or type of tests or a test panel.
  – (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information)

• Payments made to an ordering physician or his or her group practice when the specimen processing is actually performed by an in-office phlebotomist placed there by the laboratory or a third party.
The OIG listed the following characteristics, which if present in a Registry Arrangement, may be indicia of unlawful purpose under the AKS:

- Requiring physicians to perform tests with a certain frequency in order to receive compensation;
- Registries that collect data only from the tests performed by a certain laboratory;
- Compensation paid to physicians is not supported by documentation, submitted by the physicians in a timely manner, memorializing the physicians’ efforts;
- The lab offers Registry Arrangements only for tests for which it has obtained patents or that it exclusively performs.
As highlighted in the alert, this is true even if the arrangement involves payments that are consistent with fair market value, as the government’s aggressive position has shown that although it may be helpful evidence that no AKS violation occurred, *fair market value* compensation in and of itself is not a shield against AKS liability.

Even if an arrangement carves out federal healthcare program beneficiaries and only applies to non-federal healthcare program patients, it would still be a violation of AKS if the requisite intent is present.
The OIG reiterates its long-standing concern about payments from laboratories to referring physicians, specifically payment arrangements structured as a “per-click” fee taking into account the volume or value of referrals of federal health care program business.

It is important to note that the OIG restated its concerns about selecting business partners on the basis of past or anticipated referral patterns.

According to the OIG, illegal payments for specimen processing may be made directly or indirectly through marketing or other agents. Thus, third party agreements with physicians involving specimen processing will need careful review of the underlying structure to ensure no undesirable consequences under the Anti-Kickback Statute.
If any purpose of an arrangement is to award or induce such referrals, it will violate AKS.

- An AKS violation can result in penalties to parties on both sides of the arrangement, both laboratories and physicians.

- Labs and physicians desiring to enter into Specimen Processing Arrangements and Registry Arrangements must be very certain that they have no intent to pay for referrals, even if the payments are for bona fide services and are set at fair market value. Further, these Arrangements should be structured to avoid the identified suspect attributes. For example, Specimen Processing Arrangements can be set up to provide for a fair market value set-in-advance fixed fee that does not take into account individual patients, encounters or specimens.
New Spine Procedures Proposed in an ASC Setting
CMS recently released the 2015 proposed payment rule for ASCs and HOPDs. One of the key changes in the proposed rule is the addition of 10 spine codes to the ASC payable list:

- 22551 Neck spine fuse & remov bel c2
- 22554 Neck spine fusion
- 22612 Lumbar spine fusion
- 22614 Spine fusion extra segment
- 63020 Neck spine disk surgery
- 63030 Low back disk surgery
- 63042 Laminotomy single lumbar
- 63045 Removal of spinal lamina
- 63047 Removal of spinal lamina
- 63056 Decompress spinal cord
ASCA Survey for Proposed Procedures

The Centers for Medicare & Medicaid Services (CMS) is currently considering which procedures should be added to the list of ASC payable procedures for 2015. This survey gathers information on procedures that the ASC community would like to see added. This information will help ASCA advocate for the expansion of the list of procedures that CMS considers clinically appropriate for ASCs to provide to Medicare beneficiaries.

You should complete one survey for each procedure you would like added. If the code is on the inpatient only list, please do not fill out a survey, as it is not eligible to move to the ASC list at this time.

http://www.ascassociation.org/ascanewsdigest/resourcecenter/newsdigest/2014/july/newsdigest07222014#Story3
HIPAA Compliance Deadline--BAA

Business Association Agreements (BAA)

• Compliant BAAs under the old rules in place as of January 25, 2013, have until September 23, 2014, to be updated. This includes "evergreen" contracts that auto-renew without intervention.

• An evergreen provision provides that the contract (and its present terms) will automatically renew at a set time interval – usually every year. While this provides the physician with the peace of mind that the contractual relationship will carry on without interruption, it also provides a mechanism whereby the physician can force re-negotiation of certain provisions of the contract in anticipation of the renewal. This ability to re-negotiate is essential as it allows the physician to avoid “being stuck” with unfavorable terms for an untenable period of time.
• Make sure your BAA meets the current standards. As you review your BAAs, you may provide stronger language and protection for breaches, liability and indemnifications, so you will not be held liable for the actions of a business associate.

• Keep in mind, the obligation to have a BAA in place lies with the covered entity, not the service provider.

• Any new or manually renewed contracts created after January 25, 2013, needs to comply with the HIPAA revised rules by September 23, 2013.
As of September 23, 2014, all BAAs must include the following:

- A requirement that business associates must comply with the HIPAA Security Rule;
- A requirement that business associates report breaches of unsecured protected health information (PHI) to covered entities;
- A requirement that any subcontractors of the business associate agree to the same restrictions and conditions that apply to the business associate.

Business associates must enter into BAAs with their subcontractors.

All parties to the BAA should keep and maintain evidence that the BAA was fully executed.
Upon publication of the new rules on January 25, 2013, Health and Human Services (HHS) released updated HIPAA Business Associate Agreement template provisions, available at the same Web address as the old version:

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html
(Shorter link: http://tinyurl.com/7asm2qj)

As always, you should not adopt any template as is, but use it as a tool to look at your current template and agreements, identify needed changes and work with your attorney to implement those changes in a way that is legally correct for you in your state.
HIPAA increased the consequences of non-compliance for all business associates. They always have been liable to the covered entities that they serve for failure to comply with the terms of their business associate agreements.

As of September 23, 2013, business associates are directly liable to the covered entity and now HHS for failure to comply with the following HIPAA rules:
Business Associate Requirements

- Making only permissible uses and disclosures;
- Providing breach notification to a covered entity;
- Providing access to copies of electronically held PHI to a covered entity or the individual upon request;
- Disclosing PHI to the secretary for investigation into the business associate’s HIPAA compliance;
- Providing an accounting of disclosures;
- Complying with the Security Rule requirements;
- Making “reasonable efforts” to adhere to the Minimum Necessary Standard; and
- Entering into business associate agreements with subcontractors that receive PHI.
Patient Notice of Privacy Practices (NPP)

Remember, you need to review and ensure that your Patient Notice of Privacy Practices have been updated to reflect the changes to patient rights as set out by HIPAA. You may also consider modifying your NPP to remove language no longer required that addresses certain marketing activities. These now require an authorization instead. These changes needed to be implemented by September 23, 2013.

Providers were NOT required to mail out a new NPP to patients, but will need to use it, make it available and properly posted in their offices and on their websites.
As of September 23, 2013, covered entities must include a number of new statements in their NPPs.

1. The NPP must include a statement that use of and/or disclosure of any protected health information for marketing purposes and disclosures that constitute the sale of PHI require an authorization.

2. HIPAA regulations continue to require a statement that any other uses and disclosures not specified in the NPP require an authorization.

3. If the covered entity maintains “psychotherapy notes,” the NPP must include a statement that the psychotherapy notes will only be used and disclosed with the individual’s authorization.

4. If the covered entity contacts individuals for fundraising, the NPP must already state this as a separate use and disclosure. The covered entity must also include a statement in its NPP that the individual has the right to opt out of receiving these fundraising communications.
In addition to adding the new NPP requirements described above, the HIPAA Omnibus Rule removes a current requirement. Currently, an NPP must include a statement that the covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or services that may be of interest.

After March 26, 2013, this statement was no longer required to be included in an NPP. Although the statement is no longer required, covered entities may continue to include such a statement in their NPP if they so wish.
Is the EEOC Targeting Healthcare?

The EEOC files very few lawsuits in any given year, and it seeks to make the biggest impact it can with the cases it does file. Highlighting a lack of tolerance and understanding on the part of those who treat people with disabilities makes for very good press for the EEOC and very bad press for the medical profession.

For that reason, health care employers and their practice administrators need to pay particular concern to employees seeking accommodations. Employers need to be proactive in her approach and thorough in documentation and in doing so should:
EEOC sues Genesis Health Care, LLC, owner of North Carolina nursing home company for violation ADA

The employer hired a woman as a cook and dietary aide who has a physical impairment that limits her use of the left side of her body. Soon after the aide began working, her supervisor asked her what was wrong with her left arm. The aide told the supervisor that “that she did not have the full use of her left arm, but that she was still able to perform her job duties.” A few weeks later, the aide was told that the supervisor did not believe that she could perform her job duties without the full use of both arms, and she was fired.

An EEOC attorney said that “An employer cannot terminate an employee based solely on uninformed assumptions about her ability to work simply because of a disability.” The EEOC also noted the employer’s failure to offer a reasonable accommodation in its lawsuit.
According to the EEOC's lawsuit, Francisca Lee had worked as a nurse for DCI's for 14 years when she was diagnosed with breast cancer. Lee took medical leave in order to have mastectomy surgery and chemotherapy treatments.

Four months later, DCI notified Lee was being terminated for exceeding the time limit dictated by its medical leave policy, the EEOC said. This was done despite Lee being on approved medical leave and cleared by her doctor to return to work without restrictions in less than two months. Lee was told that she would have to reapply for open positions. However, when Lee did apply over two months later, she was rejected, and not long after, DCI hired a newly licensed nurse.
EEOC v DCI

EEOC San Francisco District Director Michael Baldonado added, "The purpose of the ADA is to ensure that people who are qualified and able to do the job can work without prejudice against disability to hold them back. After her doctor cleared her for work, Ms. Lee was passed over in favor of a far less qualified candidate. DCI's failure to re-hire Ms. Lee because of her disability, or record of disability, violated federal law and was just plain wrong. A healing facility such as DCI should especially understand that."
Accommodation = Help

• Employers and practice administrators need to pay particular concern to employees seeking accommodations and should be proactive in their approach with employees. Employers should:

• Carefully consider the documentation provided by the employee’s regarding their ability to return to work.

• Discuss reasonable accommodations with the employee including the possibility of a reduced work.

• Manage FMLA. Do not terminate an employee who has exhausted FMLA leave without considering the implications of the ADA.

• Document all interactions and conversations in the event the employer she needs to justify a decision not to return the employee to his or her job.
### ADA-Partial List of Qualified Disabilities

#### Physical Problems
- Physical Problem
- Asthma (or other breathing problems)
- Blindness (& partial blindness)
- Deafness (& partial deafness)
- Diabetes
- Dizziness/Balance problems
- Epilepsy
- General Hearing Difficulty
- Mobility Problems
- Neurological Problems
- Paralysis
- Physical Weakness
- Speech Problems
- Seizures

#### Emotional/Mental Problems
- Age-Related Cognitive Decline
- Any Psychiatric Condition (see exclusions below)
- Autism
- Depression
- Dyslexia
- Bipolar Disorder
- Emotionally Overwhelmed
- Panic Attacks
- Post Traumatic Stress Disorder (PTSD)
- Separation Anxiety
- Social Phobia
- Stress Problems

***NOTE: The ADA does not list all conditions or diseases that make up physical, mental, and emotional impairments, because it would be impossible to provide a comprehensive list given the variety of possible impairments***
Court Actions
The Center for Medicare Advocacy has filed a class action lawsuit against HHS over the first two levels of the Medicare appeals system, which the center alleges “rubber stamp” coverage denials at both the Redetermination and Reconsideration levels of appeals.

CMA brought the suit against HHS just weeks after the American Hospital Association also sued HHS over the backlog at the third level of the Medicare appeals process to compel the agency to meet the deadlines for reviewing an appeal.
The class action lawsuit includes four plaintiffs who the CMA says “represent thousands of Medicare beneficiaries in Connecticut who cannot get a meaningful review of their case, and instead, receive an initial denial of coverage that is essentially 'rubber stamped' at both the Redetermination and Reconsideration levels.”
In May 22, 2014, the American Hospital Association (AHA) and three member hospitals filed a lawsuit against Secretary Kathleen Sebelius, in her capacity as the Secretary of the U.S. Department of Health and Human Services (HHS), in the U.S. District Court for the District of Columbia to compel HHS to meet the statutory deadlines for the administrative review of denials of claims for Medicare reimbursements.

In late 2013, the HHS Office of Medicare Hearings and Appeals (OMHA) issued a memorandum explaining that it would be suspending the assignment of most new requests for Administrative Law Judge (ALJ) hearings for the next two years due to a massive backlog of appeals and shortage of Administrative Law Judges (ALJs).
According to the Office of Medicare Appeals and Hearings (OMHA) website:

“Due to the overwhelming number of receipts and the existing workload within the Agency, OMHA implemented a program that defers the assignment of most requests for hearing received after April 1, 2013. Under this new docketing process, new requests for hearing will be entered into our case processing system, then held until they can be accommodated on an Administrative Law Judge's docket for adjudication.”
An updated May 20, 2014 table on the OMHA website indicates that the average ALJ appeal processing time continues to grow and, as of April 2014, increased to 418.7 days.

In their complaint, the AHA, joined with several hospitals, contend that the lengthy delays in the Medicare appeals process are causing severe financial harm to Medicare providers appeals and a shortage of ALJs.
AHA lawsuit against HHS

- Baxter Regional Hospital claims that it has approximately $4.6 million tied up in the Medicare appeals process, with more than $1.7 million pending at the ALJ level.

- Covenant’s Hospitals have more than $7.6 million in system-wide claims pending in the Medicare appeals process, approximately $6.6 million of which is pending at the ALJ level.

- Rutland Hospital currently has approximately $588,000 tied up in the Medicare appeals process, of which approximately $554,000 is pending at the ALJ level.
AHA lawsuit against HHS

- Per the AHA press release, the plaintiffs allege that “excessive inappropriate denials by Recovery Audit Contractors (RACs) are the direct cause of the current backlog.”

- That AHA also alleges that the “perverse incentive” of the RAC contingency-based payments leads to excessive inappropriate denials that are typically overturned at the ALJ level according to the HHS Office of Inspector General (OIG).

- The AHA lawsuit seeks that the Court issue a “declaratory judgment that HHS’s delay in adjudication of Medicare appeals violates federal law” and to also compel HHS to comply with providing timely ALJ reviews within the statutory limit.
OMHA Options to Resolve Appeals

On June 30, OMHA posted on its website two new options for appellants seeking resolution of their appeals.

1. The first allows appellants to have their claims adjudicated using statistical sampling and extrapolation. This initiative facilitates resolution of large numbers of claims based upon resolution of a statistically valid sample.

2. The second new option for appellants uses alternative dispute resolution techniques during a facilitated settlement conference conducted by OMHA attorneys who have been trained in mediation techniques. OMHA will be monitoring the performance of these pilots and, if successful, will roll them out nationally as funding allows.
OMHA Options to Resolve Appeals

3. Finally, to bolster the processing of beneficiary appeals as their first priority, OMHA has redirected the efforts of its senior attorneys to assist in the prioritization of these appeals.

Any beneficiary who believes their case is not receiving priority consideration may contact OMHA directly by e-mail at Medicare.Appeals@hhs.gov or at OMHA’s toll free number, 855-556-8475
Thank you

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