

## HEALTH LAW YEAR IN REVIEW: HERE'S WHAT HAPPENED IN 2014 AS WE LAUNCH INTO 2015

*As the health care delivery system continues to evolve, Hall Render attorneys are committed to providing practical counsel and insight to health care providers. Below is a compilation of fifteen developments from 2014 that will continue to impact the health care industry in 2015. As the new year begins, our attorneys will continue to monitor, analyze and interpret future developments as they arise.*

### 1. TWO-MIDNIGHT RULE UPDATE

#### *Background*

In the 2014 inpatient prospective payment system ("IPPS") final rule, CMS established the "Two-Midnight Rule" in an attempt to clarify standards for appropriate inpatient admissions. CMS was concerned that hospitals, afraid of being denied inpatient Part A payment for short stays, were keeping patients in prolonged observation in order to guarantee themselves reimbursement for reasonable and necessary outpatient services while outpatients sustained greater out-of-pocket costs than they would have had they been admitted as inpatients. The Two-Midnight Rule provides that surgical procedures, diagnostic tests and other treatments are generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least two midnights *and* admits the patient to the hospital based on that expectation. CMS hoped that the Two-Midnight Rule would create more certainty for hospitals tasked with making outpatient versus inpatient admission decisions and that more inpatient admissions (as a consequence of the hospitals' greater confidence that they would get paid under Part A) would protect Medicare beneficiaries from the extra costs associated with prolonged observation (outpatient) stays.

For more information on the Two-Midnight Rule, see these articles:

- [CMS Final Rule Providing Additional Part B Payment to Hospitals Denied Part A Inpatient Payment;](#)
- [CMS Delays Full Implementation of the 2-Midnight Rule Until January 1, 2014;](#)
- [2013 Health Law Year in Review: 13 Notable Changes in Health Law in 2013;](#)
- [2-Midnight Rule 0.2% IPPS Offset Group Appeal;](#) and
- [2-Midnight Rule: CMS Proposes to Eliminate Physician Certification Statement Requirement for Most Inpatient Stays.](#)

As it turned out, the Two-Midnight Rule provoked more questions than were anticipated by CMS. In response, CMS sponsored open door fora, provided written educational materials and implemented numerous partial delays in enforcement in order to give hospitals the opportunity to adjust to the revised admission standards. Below is a summary of recent developments related to CMS's Two-Midnight Rule.

#### *Partial Delays in Enforcement*

The original enforcement date for the Two-Midnight Rule was Oct. 1, 2013; however, CMS delayed full enforcement four times over the course of 2014 with full enforcement of the rule now scheduled for **March 31, 2015**. This means CMS will continue the Medicare Administrative Contractor Probe & Educate process through March 31, 2015 and will continue to prohibit Recovery Audit Contractor ("RAC") inpatient hospital patient status reviews for dates of admission occurring between October 1, 2013 and March 31, 2015. To clarify, during this expanded enforcement delay period, physicians are expected to make inpatient admission decisions consistent with the Two-Midnight Rule even though the RACs are not permitted to review admissions for the period October 1, 2013 through March 31, 2015.

#### *68% Settlement Opportunity*

Prior to the introduction of the Two-Midnight Rule, RAC audits denied many inpatient admissions. Hospitals appealed these unfavorable RAC determinations, winning on average about 80% of them, and the appeal pipeline became so clogged that the RAC appeal process fell behind statutory deadlines for review, prompting an American Hospital Association ("AHA") lawsuit for not meeting these deadlines.<sup>1</sup> In an effort to

clear the backlog and to decrease administrative costs to Medicare and to hospitals, CMS offered hospitals and critical access hospitals the opportunity to request settlement of their inpatient status claims in the appeals process or within the timeframe to request an appeal. Any hospital willing to withdraw its pending appeals would receive a timely partial payment equal to 68% of the net allowable amount, so long as the request for settlement was submitted by October 31, 2014. The Two-Midnight Rule was an attempt to provide clarity on inpatient admission criteria in order to eliminate the repetitive cycles of RAC denials followed by hospital appeals of such RAC denials and the years-long backlog of unprocessed appeals the RAC denials engendered.

## *Two-Midnight Rule Litigation*

The CMS actuary estimated that the hospital admission clarification, subject of the Two-Midnight Rule, would cost the program an *additional* \$220 million because services previously deemed outpatient would be shifted to inpatient. To make up this additional cost for otherwise unaltered services, CMS proposed and then finalized a 0.2% reduction in IPPS payment rates. Hospitals have already felt the bite. DRG payment reductions of 0.2% began for discharges taking place on or after October 1, 2013.

On January 23, 2014, the AHA requested a hearing and expedited judicial review before the Health and Human Services Provider Reimbursement Review Board to question the validity of the 0.2% reduction in rates. Hall Render filed a large group appeal shortly thereafter, and Hall Render and the AHA coordinated their efforts on behalf of hospital plaintiffs. The AHA's Two-Midnight Rule case has finished briefing and is awaiting a decision in the District Court for the District of Columbia. There could be a decision early in 2015.

For FY 2015, which has already begun, CMS did not do another reduction, but because the standardized amount for each year starts at the base for the prior year, the FY 2015 payments are also 0.2% less than they would have been had CMS not done this offset to begin with. For this reason, Hall Render is filing another round of appeals for FY 2015.

## *CMS Eliminates Physician Certification Statement Requirement for Most Inpatient Stays*

As part of the original Two-Midnight Rule, CMS required a physician certification statement encompassing a physician admission order for inpatient services, the reason for inpatient services, the expected length of stay and the post-discharge plan of care, as applicable. Then, in the CY 2015 Outpatient Prospective Payment System ("OPPS") Proposed Rule, CMS proposed to eliminate the physician certification statement except for inpatient stays of 20 days or more and outlier cases, while retaining the physician admission order requirement. On October 31, 2014, CMS published the CY 2015 OPPS Final Rule with Comment Period and finalized its proposal to eliminate the Two-Midnight Rule certification statement requirement except for inpatient stays of 20 days or more and outlier cases. The physician admission order requirement was retained. Hospitals should continue to ensure that the medical record supports the medical necessity of an inpatient stay.

## *Legislative Development*

On November 19, 2014, the House Ways and Means Subcommittee on Health released draft legislation that addresses the repeal of the Two-Midnight Rule payment reduction, the subject of the litigation described above. The draft legislation also addresses a new hospital prospective payment system, the development of a new per diem rate for short lengths of stay and a continued moratorium of the auditing of hospital inpatient short stays through the *end* of FY 2015. (More on draft legislation below - see Physician-Owned Hospitals - 2014 Updates.)

## **2. FRAUD AND ABUSE: FALSE CLAIMS ACT/STARK LAW/ANTI-KICKBACK STATUTE ENFORCEMENT ACTIONS**

On November 20, 2014, the Department of Justice ("DOJ") announced that the United States had recovered almost \$6 billion from False Claims Act ("FCA") litigation in 2014, marking the first time the DOJ has recovered more than \$5 billion in a single year.

Not only was this the largest recovery year for the DOJ, but it makes 2014 the third consecutive year that the DOJ has announced record recoveries. The record recoveries were bolstered by over 700 whistleblower lawsuits filed on the government's behalf in 2014. Of the total \$5.69 billion recovered, almost \$3 billion was recovered in lawsuits filed by whistleblowers in *qui tam* actions under the FCA. Following is an update on five noteworthy health care-related FCA cases.

### *Case 1: Bonus Pool Distribution Methodology Defect Violates Stark*

On March 11, 2014, a hospital system agreed to pay \$85 million and enter into a corporate integrity agreement to resolve an FCA *qui tam* suit alleging violations of the Stark Law. The FCA prohibits a person from knowingly presenting, or causing to be presented, a false or

fraudulent claim to the United States government. The Stark Law prohibits a physician from making a referral for designated health services payable by Medicare to any entity with which the physician (or the physician's immediate family member) has a financial relationship unless an appropriate exception applies. The entity, in turn, may not present a claim to Medicare for designated health services furnished pursuant to a prohibited referral. Stark violations are often bootstrapped with FCA claims, resulting in a trebling of damages and huge penalties for health care organizations.

In November 2013, a federal district court held that the hospital's productivity bonus compensation methodology for the hospital's medical oncologists failed to meet the requirements of Stark's employment exception. Because the bonuses were paid out from a bonus pool that *included* revenues from designated health services (e.g., chemotherapy administration fees earned by the hospital), the court determined on summary judgment that the bonus payments impermissibly took into account the volume or value of the physicians' designated health service referrals in direct contravention of the Stark Law. Notwithstanding this substantive ruling, the court did not award summary judgment on damages in 2013 because it was unable to verify the government's \$27 million damages figure for harm to the Medicare program. A jury trial on damages was scheduled for March 2014 when the settlement was reached. For more details on the Stark Law-related aspects of this case, see Section 11 (Team-Based Compensation Arrangements) found [here](#).

A second part of this complex FCA suit was settled for \$1 million on July 8, 2014, shortly before a jury trial was scheduled to consider whether the hospital also violated the FCA by inadequately documenting the medical necessity of thousands of inpatient admissions with valid physician admission orders and by billing on an inpatient basis when the services rendered should have been billed at the lower outpatient rate. The court held that the hospital's potential violation of a Medicare *condition of participation* related to the absence of admission orders would not render otherwise valid Medicare claims "false" and therefore actionable under the FCA. In this case, the court affirmed the principle that violations of conditions of participation do not rise to the level of being FCA violations. Interestingly, CMS has since reclassified the physician order requirement for an inpatient admission from a "condition of participation" to a "condition of payment." Had this change been in effect during the time period of the inpatient admissions in question, the improper admission-related settlement amount likely would have been much greater.

#### *Case 2: Federal Court Says Stark Applies to Medicaid Claims*

On April 14, 2014, a federal court approved a \$7 million settlement of a state and federal FCA *qui tam* case filed by a whistleblower who alleged that a children's hospital violated the Stark Law by overcompensating referring physicians. The hospital will pay \$4 million to the federal government and the \$3 million to the state. One of the main issues presented in this case was whether Stark applies to Medicaid claims. In 2010, more than 70% of patient care at the hospital was paid by the Medicaid program. There was very little Medicare business as is typical in a children's hospital.

The whistleblower is a former director of operations who assisted in the development of the physician compensation plan and was responsible for managing physician staffing and the "on-boarding" of new physicians. She alleged that the hospital began to lose market share, embarked on an aggressive recruitment campaign and paid compensation in excess of fair market value, contrary to the parameters in the compensation plan and the Stark Law. The hospital filed a motion to dismiss based on its view that Stark does not apply to Medicaid claims. The federal district court relied on language in recent decisions<sup>2</sup> and ruled that the Stark Law applies to Medicaid claims even though CMS never implemented through rulemaking a 1993 amendment to the Stark Law extending aspects of the Medicare prohibition on physician self-referral to Medicaid. The hospital attempted to argue that since 42 USC §1395nn (where Stark is codified) is located in the subchapter governing Medicare, Stark is not applicable to Medicaid, located in a different subchapter. The court soundly rejected this argument. While the DOJ did not intervene in the case, it submitted a statement of interest clearly articulating its position that the Stark Law applies to Medicaid claims.

This case also raised a couple of additional interesting points related to "fair market value." First, the whistleblower tasked with developing the physician compensation plan determined that the guaranteed base salary should fall between the 25th percentile and the 75th percentile *and was unable to find any data that would support exceeding the 75th percentile*. The whistleblower's reasoning seems to suggest that compensation above the 75th percentile is above fair market value. We believe this is wrong for at least two reasons: 1) the Stark regulations do not establish salary survey percentile ranges as the prescriptive measure of fair market value; and 2) whether a particular compensation package is "fair market value" depends on all the facts and circumstances of a particular arrangement; slavish reliance on percentiles alone is insufficient.

Another potential takeaway based on the pleadings in this case is that once a hospital establishes a compensation plan and determines the range of fair market value, it should not deviate from the compensation plan and pay outside the established range. In this case, physicians were paid at the 90th percentile or higher even though the hospital approved a plan calling for compensation set at the 25th to 75th percentile. It is risky to establish a compensation plan based on objective data and then not follow the plan.

Hospitals and other health care providers must monitor FCA cases carefully to see if the trend toward inclusion of Medicaid referrals in the Stark web continues. They should also engage the assistance of legal counsel to identify appraisers who know the local health care market and who can assist with developing compliant compensation plans. Once a plan is approved, the hospital/health care provider should follow it.

### *Case 3: DOJ Takes a Look at IOASE, Special Rules for Profit Shares - Case Settles Before Going to Trial*

On July 21, 2014, a hospital system agreed to pay \$24.5 million and to enter into a five-year corporate integrity agreement to resolve government allegations that it violated the FCA by entering into compensation arrangements with referring physicians that violated the Stark Law and the Anti-Kickback Statute.

The federal government intervened in this *qui tam* suit in August 2013. It alleged that from 2005 through 2011, a hospital system submitted millions of dollars of false claims to the Medicare program for designated health services ("DHS"), including clinical laboratory and diagnostic imaging services. While certain hospital system and related clinic entity physician employment agreements specifically stated that Medicare/Medicaid DHS collections would be paid to physicians under a "predetermined formula" and *not* paid as a percentage of collections *directly attributable* to the volume or value of the DHS referred by each physician as required by the Stark Law, in practice, there was no predetermined formula used to determine the physicians' "preset Stark bonuses" and such bonuses, the government alleged, did correlate to their individual referrals-related collections, as evidenced by the information in certain bonus spreadsheets produced for government inspection.

Moreover, the government further alleged that the physicians did not meet the definition of a "group practice" under Stark and so could not rely on the in-office ancillary services exception to Stark that might have exempted the physicians' referrals from Stark if the compensation methodology was compliant. Again, the compensation did not meet the Stark regulations special rules on productivity bonuses and profit shares. Finally, the government devoted a good portion of its complaint in intervention, describing the hospital system's knowledge of its Stark and AKS violations. For more details on this case, see Section 11 (In-Office Ancillary Services Exception) found [here](#).

Because this case was settled, the court did not have an opportunity to fully analyze and rule on the physician group's compliance with the in-office ancillary services exception and "group practice" requirements.

### *Case 4: Broad Coordination and Cooperation Between Government Agencies Yields \$98 Million FCA Settlement*

On August 4, 2014, the DOJ announced a settlement of \$98.15 million with the nation's largest operator of acute care hospitals ("Health System"). The settlement resolves multiple lawsuits filed under the *qui tam* whistleblower provisions of the federal FCA. The settlement illustrates the trend towards broad coordination and cooperation between disparate government agencies, in this case, U.S. Attorneys' offices distributed across five states, the DOJ, OIG, the Department of Defense's Defense Health Agency - Program Integrity Office and the FBI. In addition, the case is notable for the number of hospitals involved (119) and the number of whistleblowers who filed suit (9).

The U.S. alleged that from 2005 through 2010, the Health System "engaged in a deliberate corporate-driven scheme" to increase inpatient admissions of federal health care program beneficiaries at the Health System's affiliated hospitals. According to the government, a number of inpatient admissions from hospital emergency departments were "not medically necessary." During the same time period, one of the Health System's hospitals was alleged to have presented false claims to Medicare for certain cardiac and hemodialysis procedures performed on an inpatient basis instead of the less costly and medically appropriate outpatient basis. Further, from 2007 through 2012, this same hospital is alleged to have billed Medicare for services referred to it by a physician who was offered a medical directorship in violation of the Stark Law.

Hospitals should continue to be vigilant with their billing practices and should pay special attention to the latest CMS guidance on the criteria and requirements for inpatient versus outpatient admissions. The payment rules for "short stays" are not a settled area of the Medicare reimbursement framework. Whistleblower suits under the FCA continue to increase. Hospitals must be certain to take seriously and



investigate immediately any compliance or health care fraud concerns raised by employees, contractors and medical staff members.

#### *Case 5: Another Hospital System Settles over Alleged FCA Violations for Inappropriate Inpatient Admissions*

In another set of facts pertaining to inpatient admissions deemed not medically necessary, on October 30, 2014, a large hospital system agreed to pay the government \$37 million to settle FCA charges that 13 of its hospitals submitted false claims to Medicare and TRICARE by admitting patients as inpatients when they could have been treated on a less costly outpatient basis.

Specifically, from 2006 through 2010, these hospitals were alleged to have billed elective cardiovascular procedures such as stents and pacemakers as inpatient procedures when they could have been billed as outpatient surgeries. Further, from 2000 through 2008, four hospitals were alleged to have billed Medicare for inpatient elective kyphoplasty procedures (used to treat osteoporosis-related vertebral fractures) when these minimally invasive procedures could have been performed on an outpatient basis. Finally, the government alleged that from 2006 through 2010, 13 hospitals admitted patients for certain common medical diagnoses - conditions, again, that could have been provided safely on an outpatient basis.

As is typical in these types of settlements, the claims resolved were allegations only, and the hospital system was not determined to be liable. The practical takeaway is that hospitals must thoroughly educate their medical staffs on inpatient admission criteria and appropriate documentation, and utilization review personnel must ensure that the medical record can support an inpatient admission before it is billed as such.

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FCA activity in the health care field is reminiscent of the "I Love Lucy" candy factory episode where the chocolates are coming faster and more furiously down the conveyor belt. We anticipate that fraud and abuse cases will figure prominently in Hall Render's 2015 "Health Law Year in Review."

### **3. ALLINA V. SEBELIUS - BIG WIN FOR HOSPITALS IN MEDICARE APPEALS LITIGATION**

In the world of Medicare appeals litigation, hospitals achieved an important victory on April 1, 2014. In *Allina v. Sebelius*, the District of Columbia Court of Appeals held that CMS's rule allowing it to count Medicare C days as Medicare A days in the Medicare fraction of the Disproportionate Share Hospital ("DSH") adjustment was invalid because CMS failed to follow required rulemaking procedures.

At issue was which fraction of the DSH formula Part C Medicare Advantage Days ("Medicare C Days") should be included when determining a hospital's DSH payments. (Medicare DSH payments are based on the sum of a hospital's days for patients entitled to Medicare and SSI divided by its total Medicare days (Medicare fraction), plus the hospital's days for patients eligible for Medicaid divided by its total days (Medicaid fraction)). The Secretary first proposed a rule saying the Medicare C Days would be counted in the Medicaid Fraction, an approach more favorable to hospitals. However, in the publication of the final rule, the Secretary did exactly the reverse, requiring the Medicare C Days to be counted in the Medicare fraction, an approach less favorable to hospitals.

While the Court of Appeals indicated "the statute unambiguously requires that Part C days be counted in one fraction or the other," it found the lower court went too far in ordering CMS to include the Part C days in the Medicaid fraction. It found the question of remedy was not properly before the court, and therefore CMS must be allowed to adjudicate on a case by case basis how the Medicare C days should be treated but without the benefit of the invalidated regulation.

CMS did not seek to appeal *Allina* nor has it issued any instructions to the Medicare Administrative Contractors on the correct handling of Medicare C days. So far, in subsequent filings in the *Allina* case, CMS has made it clear that it plans to adjudicate the issue further at the Provider Reimbursement Review Board ("PRRB"). Hall Render believes the PRRB does not have the authority to decide this issue. It plans to seek expedited judicial review to ask the District of Columbia District Court for a ruling that prohibits CMS from including the Part C days in the Medicare fraction and allows the corresponding Part C days to be counted in the numerator of the Medicaid fraction.

### **4. BURWELL V. HOBBY LOBBY - SUPREME COURT RULES CLOSELY HELD FOR-PROFIT CORPORATIONS WITH RELIGIOUS OBJECTIONS ARE EXEMPT FROM ACA'S CONTRACEPTIVE MANDATE**

On June 30, 2014, the U.S. Supreme Court issued a 5-4 decision in *Burwell v. Hobby Lobby Stores, Inc., et al.* ("*Hobby Lobby*") that extends certain religious freedom protections to closely held for-profit corporations. The Supreme Court ruled that the federal government cannot impose the contraceptive mandate on closely held for-profit corporations that have religious objections because the mandate violates the

religious rights of such corporations under the Religious Freedom Restoration Act of 1993 ("RFRA").

## *Background*

The Patient Protection and Affordable Care Act of 2010 ("ACA") requires that employers' group health plans furnish preventive care and screenings for women without any cost-sharing requirements. The ACA directed HHS to define preventive care. In doing so, HHS included 20 contraceptive methods that have been approved for use by the Food and Drug Administration ("FDA"). Religious objectors have contended that some of these contraceptive methods are abortifacient drugs. In partial recognition of these objections, HHS and the FDA exempted churches and certain closely related organizations and provided an accommodation to these non-profit religious organizations.

Under the RFRA, the federal government is prohibited from substantially burdening a person's exercise of religion even if the burden results from a rule of general applicability, unless the government demonstrates that application of the burden to the person is in furtherance of a compelling governmental interest *and* is the least restrictive means of furthering that compelling governmental interest.

In the *Hobby Lobby* case, three closely held for-profit corporations challenged the application of the contraceptive mandate based on religious objections. The owners had "sincere Christian beliefs that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point."

## *The Ruling*

The Supreme Court reasoned that a closely held for-profit corporation is a "person" for purposes of the RFRA and can share the sincere religious beliefs of a corporation's shareholders, officers and employees. Further, it opined that the contraceptive mandate violates the RFRA because it substantially burdens the exercise of religion and is *not* the least restrictive means of furthering a compelling governmental interest. The Court left open whether the holding might apply to other types of entities such as LLCs and partnerships.

## **5. PROPOSED RULE TO AMEND AKS SAFE HARBORS AND CMP RULES - OIG'S NOD TO A CHANGING HEALTH CARE DELIVERY LANDSCAPE**

On October 3, 2014, OIG published a proposed rule that would amend the AKS safe harbors and the civil monetary penalty ("CMP") rules to insulate patient to provider and provider to provider financial relationships that increase access, improve quality and decrease costs of health care without harming Medicare beneficiaries or the federal health care programs. Some of what OIG intends to codify in the regulations derives from statutory changes in the Medicare Modernization Act of 2003, the Affordable Care Act of 2010 and the Balanced Budget Act of 1977. The OIG proposed rule is a nod to a vastly changed health care delivery system that focuses on cost containment, patient centeredness and improving access to care. Following are some of the proposals.

### *Amended Definition of "Remuneration" Permits Four Exceptions to CMP Law Prohibition on Beneficiary Inducements*

OIG proposed to codify four exceptions to the definition of the term remuneration as originally set forth in the ACA. These exceptions are summarized below:

- Any remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs;
- The offer or transfer of coupons, rebates or other rewards from a retailer if the program meets certain requirements;
- The transfer of items or services by a person: that are not offered as part of an advertisement or solicitation; that are not tied to the provision of other items or services reimbursed under a federal health care program for which there is a reasonable connection between the items or services and the medical care of the individual; and for which the person providing the items or services determines in good faith that the individual is in financial need; and
- Waivers of cost-sharing for the first fill of a generic drug for Medicare Part D beneficiaries.

### *AKS Safe Harbor Changes*

OIG proposed the following AKS safe harbor changes:

- New safe harbor to protect free or discounted local transportation subject to a number of requirements, including: the transportation cannot be of the "luxury" variety; it must be limited to 25 miles; it can only be offered to established patients; it cannot be publicly

advertised; and the transportation cannot result in "per beneficiary" compensation to drivers and others arranging for the transportation;

- Safe harbor to protect discounts on the price of a manufacturer's "applicable drugs" when provided to "applicable beneficiaries" under the Medicare Gap Discount Program;
- Safe harbor to protect any remuneration between a Federally Qualified Health Center and a Medicare Advantage organization pursuant to a written agreement that meets certain requirements; and
- Two new protections added to waiver of beneficiary coinsurance and deductible amounts safe harbor:
  - Medicare Part D cost-sharing waivers by pharmacies for the needy; and
  - Cost-sharing waivers for emergency ambulance services furnished by state- or municipality-owned service providers.

#### *OIG Proposed a Narrower Interpretation of the Phrase "Reduce or Limit Services" to Ensure Gainsharing Does Not Violate the CMP Law*

The CMP Law prohibits a hospital from knowingly making a payment to a physician as an inducement to reduce or limit services provided to federal health care program beneficiaries. Programs that seek to share cost savings with physicians who reduce costs while maintaining quality of care are known as "gainsharing" programs. In light of the technical prohibition under the CMP Law, gainsharing programs have been the subject of numerous requests for OIG advisory opinions, many of which have been approved by OIG if these programs protect beneficiaries from any negative effects of cost-saving measures. There have also been gainsharing demonstration projects conducted by CMS. In recognition that payment for cost reduction can be a win-win for federal health care programs and their beneficiaries, OIG is considering definitions that would narrowly interpret "reduce or limit services" so that gainsharing programs are not per se illegal under the CMP Law.

#### **6. PRIVATE USE OVERHAUL: IRS EXPANDS REV. PROC. 97-13 SAFE HARBORS; PROVIDES GUIDANCE FOR PARTICIPATION IN ACOS**

On October 24, 2014, the IRS released an advance version of [Notice 2014-67](#) that: (1) adds a new five-year safe harbor to Revenue Procedure 97-13 ("Rev. Proc. 97-13") and provides for the inclusion of quality-based incentive payments in management and service contracts for facilities financed with tax-exempt bond proceeds; and (2) offers interim guidance for determining whether a state or local government entity or 501(c)(3) organization with outstanding tax-exempt bonds will be considered to have private business use of its bond-financed facilities as a result of its participation in the Medicare Shared Savings Program ("MSSP") through an Accountable Care Organization ("ACO").

##### *Expansion of Rev. Proc. 97-13 Safe Harbors*

The new Rev. Proc. 97-13 safe harbor dramatically increases flexibility for health care providers when entering into management and service contracts. The new safe harbor allows for contracts of up to five years with no need for the agreement to be terminable prior to the end of five years. Compensation may be based on essentially any combination of methodologies so long as it does not include both revenues and expenses. In addition, the notice expands Rev. Proc. 97-13 to permit annual incentive payments either as a stated dollar amount or a tiered system of stated dollar amounts based on the level of performance achieved, so long as they are based on "the quality of the services provided...rather than increases in revenues or decreases in expenses of the facility."

##### *Private Use Guidance for ACOs Participating in the Medicare Shared Savings Program*

The IRS has also provided interim guidance for qualified users, including 501(c)(3) hospitals, participating in the MSSP through ACOs with for-profit participants, such as physicians, post-acute care providers and insurers. The proposed guidance does NOT include analogous arrangements with private payors.

Pursuant to such guidance, participation in the MSSP through an ACO will not, in and of itself, result in private business use if:

1. The terms of the qualified user's participation in the MSSP through the ACO are set forth in advance in a written agreement negotiated at arm's length.
2. CMS has accepted the ACO into and has not terminated the ACO from the MSSP.

3. The qualified user's share of economic benefit derived from the ACO is proportional to the benefits or contributions the qualified user provides to the ACO.
4. The qualified user's share of the ACO's losses, including its share of the MSSP losses, does not exceed the share of ACO economic benefits to which the qualified user is entitled.
5. All contracts and transactions entered into by the qualified user with the ACO and the ACO's participants and by the ACO with the ACO's participants and any other parties are at fair market value.
6. The qualified user does not contribute or otherwise transfer the property financed with tax-exempt bond proceeds to the ACO unless the ACO is also a qualified user.

Hall Render expects that few ACOs or analogous arrangements with private payors will neatly meet this safe harbor. The IRS has requested public comment on this proposal, and comments must be submitted by January 22, 2015. Going forward, non-profit hospitals that participate in ACOs with for-profit participants should have such arrangements reviewed by bond counsel, ideally, early in the drafting process. In addition, such hospitals should consider providing comments to the IRS about the proposed guidance.

## **7. SUPREME COURT GRANTS CERTIORARI IN *KING V. BURWELL* EVEN IN THE ABSENCE OF A FEDERAL CIRCUIT CONFLICT**

On November 7, 2014, the Supreme Court agreed to hear *King v. Burwell* concerning whether the IRS may permissibly promulgate regulations to extend tax credit subsidies to individuals purchasing health care coverage on health care exchanges established by the federal government under §1321 of the ACA. The Court's decision to grant certiorari seems remarkable to some Court observers. It is unusual for the Supreme Court to grant certiorari in the absence of a federal circuit court conflict - at the time of the certiorari decision, there was none. And in this particular case, at the time certiorari was granted, a hearing was pending in the D.C. Circuit on a factually similar case, *Halbig v. Burwell*, so stakeholders would not have to wait long to see how the D.C. Circuit ruled.<sup>3</sup> **The Supreme Court has scheduled oral arguments for *King* on March 4, 2015.**

The petitioners in the case, *King et al.*, opposed the requirement that individuals be required to purchase health coverage or suffer a tax consequence (the so-called individual mandate). But for the subsidies, the petitioners argued, they would have been eligible for a "hardship exemption." They also argued that tax credits can be issued only to individuals who purchase insurance in a state-established exchange and that Congress intended this outcome to encourage states to establish their own exchanges lest their citizens be deprived of the subsidies available only to citizens of states with state-established exchanges.

*King* highlights an apparent conflict between different sections of the ACA. §1321, which provides that if a state does not establish an exchange, the federal government shall "establish and operate such exchange within the state." However, §1401 provides that tax subsidies may be granted to eligible individuals meeting certain income level guidelines who purchase insurance through an exchange established by the state. Opponents of the ACA, like the petitioners, believe persons who purchase health insurance on a federal exchange are ineligible for tax credit subsidies because such subsidies only are available to those who purchase coverage on a state exchange. Related, they contend the IRS exceeded its statutory authority in promulgating regulations that allow federal exchange purchasers to receive the tax credit subsidies provided for in the ACA.

In *King*, the federal government argued, essentially, that a federal exchange is really a state exchange administered by the feds on behalf of the state. Further, Congress intended to extend the tax benefit to all eligible persons, whether they purchased coverage on a federal or state exchange, in order to increase access to health insurance - a goal at the very heart of the ACA. A three-judge panel of the U.S. Court of Appeals for the Fourth Circuit in Richmond, Virginia agreed with the federal government, and on July 22, 2014, the court held that the IRS's rulemaking was a "permissible exercise of the agency's discretion."

The same day that the Fourth Circuit issued its ruling in *King*, the D.C. Circuit issued a contrary ruling in *Halbig v. Burwell*, a similar case. However, on September 4, 2014, the D.C. Circuit vacated the panel's decision and agreed to hear the case en banc with oral arguments scheduled for December 17, 2014.

On July 31, 2014, the petitioners in *King* petitioned the Supreme Court for certiorari. Certiorari was granted on November 7, 2014, notably, after the *Halbig* decision had been vacated and before oral arguments were scheduled in the *Halbig* case; in other words, the Supreme Court granted certiorari at a time when no circuit court conflict existed on the matter in dispute. The *Halbig* case is being held in abeyance



pending the outcome of *King* before the Supreme Court.

The decision in *King* could have a major effect on the viability of the ACA if millions of low-income individuals living in states with federal exchanges are deemed ineligible to receive federal subsidies and, as a consequence, cannot afford to purchase coverage. Proponents of the ACA say the absence of these individuals in the insurance pool will disrupt the risk mitigation provisions vital to the ACA's sustainability.

## **8. INSTITUTE OF MEDICINE RELEASES REPORT RECOMMENDING FUNDAMENTAL TRANSFORMATION OF GRADUATE MEDICAL EDUCATION FUNDING STRUCTURE**

On July 29, 2014, the Institute of Medicine ("IOM") released a report entitled "Graduate Education That Meets the Nation's Health Needs" ("IOM Report"). The IOM Report calls for fundamental changes to the current graduate medical education ("GME") financing and oversight structure with the following goals: better physicians; better aligned physicians (diversity, the right specialties and cultural competence); and innovation in GME training, transparency and accountability all within a performance-based system.

The IOM Report makes the following specific recommendations:

1. Maintain Medicare GME as part of the Medicare system so GME funding is linked to a long-standing entitlement system likely to endure.
2. Delink GME reimbursement from Medicare patient volume as physicians treat the entire population, not just Medicare patients. The current formula link between Medicare hospital inpatient volume and GME reimbursement also disadvantages the community-based and non-hospital sites where most physicians will practice for the bulk of their careers.
3. Move GME funding away from the teaching hospitals to the program sponsors over the next 10 years or sooner. Not all "program sponsors" are teaching hospitals; some are educational institutions and health centers.
4. Eliminate direct GME expenditures and indirect medical education funding structure and replace this system with an operational fund to support existing GME programs and a new GME "transformation fund" to support innovation and new GME programs in underserved areas and needed specialties such as primary care.
5. Institute a national per resident amount, calculated by taking total current payment in a base year divided by the number of residents trained in that year subject to geographic adjustment.
6. Condition the ability to continue to receive GME funding on new performance-based measures established nationally.

To implement the IOM Report's recommendations for GME funding overhaul, Congress would have to pass legislation. This is not a fait accompli as not all stakeholders think the IOM's recommendations are desirable. For example, the Association of American Medical Colleges states that the proposal to "radically overhaul graduate medical education (GME) and make major cuts to patient care would threaten the world's best training programs for health professionals and jeopardize patients, particularly those who are the most medically vulnerable." Further, the American Medical Association "appreciates" the IOM's efforts, but it remains "concerned about the need to recognize the nation's potential physician shortages and the need for adequately funded physician training."

In anticipation of at least the possibility of an overhaul, Hall Render recommends that hospitals consider doing the following:

- Perform a GME self-assessment so the hospital understands the current state of Medicare GME funding in order to react swiftly if reform occurs; and
- Accurately and fully report ALL GME costs and all resident time being supported *even if the hospital is over its cap and won't benefit under the current system*. Maximizing total appropriate costs and teaching time may lead to more funding under a new GME system if payments are linked to recent GME statistics history.

For more details, click [here](#).

## **9. PREMIUM SUPPORT PROGRAMS - WHERE DO WE STAND?**

In 2014, we saw CMS issue a fair amount of guidance on a third party's ability to provide premium support to individuals purchasing a qualified health plan ("QHP") through a federal or state marketplace. Unfortunately, this guidance was at times confusing and has raised a number of questions related to CMS's authority to regulate conduct associated with non-governmental programs.<sup>4</sup> For example, in its February 7, 2014 FAQ Memo, CMS indicated that private, not-for-profit foundations could provide premium support payments on behalf of

QHP enrollees who satisfied defined income criteria, provided that the foundation did not consider the enrollee's health status and the premium support payments covered an entire policy year. Then, in CMS's interim final rule, which was issued on March 14, 2014, CMS took the opportunity to reiterate its previously stated concerns about third party premium support payments and further encouraged insurers to reject such payments, with no mention of the guidance outlined in its February 7, 2014 FAQ Memo.

Given the conflicting guidance from CMS on the issue of premium support payments, where do we stand on a health care provider's ability to provide premium support payments through its charity care program? In the most recent guidance issued by the HHS on May 21, 2014, then Secretary Kathleen Sebelius confirmed that private, not-for-profit foundations can utilize a properly structured premium support program to make premium payments on behalf of QHP enrollees. Such a program must, in order to comply with CMS's safe harbor standards, at a minimum:

- Make premium support payments based on defined income criteria and not on a QHP enrollee's health status; and
- Provide premium support payments that cover an entire policy year.

It is important to note that this latest guidance does not clarify what HHS is referring to when it uses the term "private, not-for-profit foundations" and does not broaden HHS's stance on hospitals and other health care providers' ability to directly make premium support payments on behalf of QHP enrollees. However, given the context surrounding this most recent guidance, it arguably provides further support for the position that a health system may pay a QHP enrollee's premium under a properly structured program via a related private, not-for-profit foundation. As such, we continue to believe that hospitals can make premium support payments as part of their charity care programs if the premium support program is appropriately crafted. We also believe that a premium support program designed to expand an enrollee's access to health care and not reduce patient choice would be viewed favorably.

Finally, it is important to remember that state law, and in particular state insurance laws, must also be considered before implementing a premium support program. This may be particularly significant for health systems with an affiliated insurance company.

## **10. PHYSICIAN-OWNED HOSPITALS - 2014 UPDATES**

The past year brought many exciting changes to physician-owned hospitals. Not only did CMS approve its first physician-owned hospital expansion request, but new guidelines for data sources and other application requirements were proposed and finalized. Physician-owned hospitals that potentially meet the expansion criteria and are interested in expanding the number of their beds, operating rooms and/or procedure rooms should be encouraged by these developments. In addition, draft legislation introduced by the House Ways and Means Health Subcommittee could amend the physician-owned hospital expansion prohibition to permit any physician-owned hospital the opportunity to apply for an expansion without having to meet special qualifications.

### *CMS Approved First Physician-Owned Hospital Expansion Request*

On October 31, 2014, CMS issued a final notice approving a physician-owned hospital's request for an exception to the ACA's expansion limitations imposed on physician-owned hospitals. Under the ACA's amendments to the Stark Law, a physician-owned hospital cannot expand the aggregate number of operating rooms, procedure rooms or licensed beds beyond the number for which the hospital was licensed on March 23, 2010. The Secretary of Health and Human Services may grant an exception to this limitation for physician-owned hospitals that qualify as an "applicable hospital" or a "high Medicaid facility." In May 2014, CMS published notice in the Federal Register that a physician-owned hospital had requested a high Medicaid facility expansion exception. CMS solicited comments from individuals and entities in the community where Lake Pointe Hospital (the applicant) was located. CMS's approval allowed the physician-owned hospital to add 36 additional beds to its facility on the hospital's main campus. CMS's approval of the Lake Pointe Hospital Application provided valuable insight into how CMS might treat future expansion exception applications.

### *CMS Proposed Regulations and Issued Amended Final Rule Impacting Physician-Owned Hospital Expansion Requests*

On July 14, 2014, CMS published a proposed rule that would allow physician-owned hospitals to use additional data sources to support requests for exceptions to the ban on expansion for physician-owned hospitals. After receiving several comments on the proposed rule, CMS published an amended final rule on November 10, 2014.

The final rule addressed regulatory changes to: allow for the use of supplemental data; revise the fiscal year standard; continue the use of community input; revise notice requirements; and amend the timing of CMS's review. The final rule allows the use of "external data

sources" in certain circumstances to determine the: (i) annual percentage of Medicaid inpatient admissions of the physician-owned hospital; (ii) average percentage of Medicaid inpatient admissions of all hospitals in the county in which the "applicable hospital" requesting expansion is located; and (iii) annual percentage of Medicaid inpatient admissions of any other hospital in the county in which the high Medicaid facility requesting expansion is located. This was intended to remedy certain deficiencies identified in Healthcare Cost Report Information System ("HCRIS") data. However, CMS also noted in the final rule that it had recently revised the information required on hospital cost reports such that Medicaid Managed Care discharges will eventually be included in the HCRIS data. As such, the 2015 Final Rule states that the use of external data sources will only be permitted until such time that available HCRIS data includes Medicaid Managed Care discharge data.

While the use of supplemental data may be the most monumental change addressed by the final rule, several other modifications are of significance to physician-owned hospitals considering expansion requests. CMS opted to bifurcate the fiscal year standard for Medicaid inpatient admissions and bed capacity/occupancy in the final rule. The final rule also now requires a requesting physician-owned hospital to provide actual notification directly to hospitals whose data are part of the comparisons data used in the hospital's application. CMS has also provided itself with additional time to review expansion requests that utilize supplemental data in the calculations.

#### *Annual Reporting Requirement Became Effective March 1, 2014*

CMS requires physician-owned hospitals to file a form CMS-855A, reporting individual physician ownership and investment interest data at least once annually. The first reporting period was for CY 2013. However, because of delays in communicating the information to stakeholders, the reporting requirement, technically, did not become effective until March 1, 2014. Failure to file this information on time could result in a permanent loss of the physician-owned hospital's grandfathered status provided under the Stark Law whole hospital and/or rural provider exception. In addition, 42 CFR 424.516(e)(1) addressing additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program requires hospitals to report to CMS within 30 days if there is a change of ownership or control. Thus, redemption of a physician or changes in units would constitute a change of ownership or control triggering that 30-day window to file CMS Form-855A.

#### *Ongoing Legislative Activities*

The House Ways and Means Health Subcommittee's draft legislation (referenced above in Two-Midnight Rule Update) includes a repeal of the expansion prohibition imposed on physician-owned hospitals by the ACA.

The draft bill would amend the criteria under which, if satisfied, a physician-owned hospital would be grandfathered under the ACA prohibition on new physician-owned hospitals. The amendment is designed to provide relief to physician-owned hospitals that were under construction but did not yet have a provider agreement by December 31, 2010.

In addition, the draft bill would amend the definition of "applicable hospital" to mean "a hospital that does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital that discriminate against such beneficiaries." In effect, the amendment would eliminate nearly all requirements that a physician-owned hospital currently must meet in order to be eligible to petition the Secretary to grant an exception to the expansion prohibition.

## **11. POST-ACUTE UPDATE**

#### *Home Health Face-to-Face Requirement Changing for the Better?*

On November 6, 2014, CMS published the CY 2015 Home Health Prospective Payment System Final Rule ("Final Rule"). In the Final Rule, CMS eliminates the face-to-face requirement. Instead, the physician's record will serve as the source of documentation. To be clear, the Final Rule does not eliminate the ACA-mandated face-to-face encounter between physician and Medicare beneficiary before the physician can certify the patient's homebound status. However, it eliminates the need for the certifying physician to provide a *narrative* explaining how the findings of the face-to-face encounter support the certification and services ordered.

The impetus for this change was the large number of claims rejected, primarily due to failures to comply with the face-to-face narrative requirement. CMS recognized that these rejections had resulted in the recoupment of significant dollars and placed a great burden on not just the home health industry but also on physicians, patients and others in the long-term care continuum. With the narrative eliminated, CMS proposes that auditors could rely upon documentation in the patient's physician records to support the physician's certification that the

patient is confined to the home and in need of the services ordered.

Although encouraged by the changes in the Final Rule, home health providers have reserved judgment because there is some question as to how physicians and home health agencies will work together where home health agencies' reimbursement is dependent on the physician's documentation. Despite this concern, CMS noted in the Final Rule that providers will need to produce, as part of an ADR or other audit, the physician's documentation.

Reliance on the physician's documentation is not all bad. In fact, the change may provide home health agencies with a greater ability to address the content of the physician's supporting documentation. This is important because, currently, agencies do not have an opportunity to impact or inform the physician's narrative. While CMS makes it clear that documentation supporting the certification by the physician must be readily available for audit, CMS states that it expects the findings from the agency's initial assessment would be communicated to the certifying physician and that the certifying physician "can incorporate this information into his/her medical record for the patient and use it...to support his/her certification of patient eligibility." This means the agency staff could conduct the initial assessment upon referral of a patient and forward the findings of that assessment for review by the physician. The physician will then be able to sign off on the certification and incorporate the agency's assessment into his/her medical record. The agency's assessment will then be used by the certifying physician to develop the plan of care and also *support the certification of patient eligibility*. In other words, the agency can generate, as part of its assessment, documentation supporting the patient's homebound status and need for care, and then the physician can incorporate this documentation into his/her medical record and rely upon it. At that point, *the agency* will know the physician's record supports the certification.

Providing supplemental information on the patient's condition does not amount to "writing the physician's narrative for the physician." It is simply an opportunity for the agency to communicate the findings of the assessment back to the physician. The physician can then, by reviewing and signing, incorporate this supplemental information into the physician's record. This will result in greater communication between the agency and physician and could potentially create additional supporting documentation. CMS appears to be recognizing that, in this context, it is reasonable to allow the agency, which must perform a comprehensive assessment, to communicate that information to the physician as part of developing the plan of care. It only makes sense to allow that information to be incorporated into the physician's record.

This aspect of the Final Rule appears to be a significant improvement over the existing narrative requirement because it allows for more agency involvement. It should be noted that physicians working with agencies must be willing to accept and incorporate an agency's assessment into the physician clinical record. Physicians (and to the extent applicable, their employers) might recognize this as an opportunity to streamline this process, save time on the front end and ensure accuracy of records. They might also not be receptive to this sort of "give and take," in which case agencies will be dependent upon whatever is in the physician's documentation. That could actually be worse than the current narrative requirement.

In light of this possibility, agencies should begin educating physicians on this change. An agency's referring physician will need to understand that additional supporting information from the home health agency can be relied upon by the physician if reviewed and signed by the physician. Referring physicians should understand how this will reduce their workload from the current narrative model. Agencies will want their referring physicians to think this is a good thing because it will increase the likelihood of being able to utilize this option to ensure "face-to-face" compliance.

Although CMS's comments provide little concrete guidance, it may be possible to address this communication without sending the physician a complete OASIS assessment tool. We expect CMS may issue further sub-regulatory guidance, and this will inform the best communication process between physicians and home health agencies. For example, providers may consider expanding their intake assessment process so that it also generates an additional, separate supplemental document that clearly states nurses' findings and how they support homebound status and medical necessity. This would essentially be a summary of the results of the comprehensive assessment that links the assessment findings to the plan of care and eligibility criteria. This additional document will ultimately be transmitted back to the physician to be reviewed, signed and incorporated into his/her medical record in support of the certification. Although the agency prepared it, this is different than saying the agency can draft the narrative. In summary, the elimination of the face-to-face narrative may be a win for the home health industry, referring physicians and patients.

*Caution: Pay No Mind to the Department of Labor's Temporary Non-Enforcement Policy Relating to the Companionship Services Exemption*



Those in the home health, hospice and private duty care industries are well aware of impending changes to the Companionship Services Rule ("Rule") by the Department of Labor ("DOL"). By way of background, the Fair Labor Standards Act requires employers to pay all non-exempt employees minimum wage and a premium for hours worked in excess of forty hours in a workweek. Since the late 1980s, home health, hospice and private duty employers have operated under an exemption to the Rule that allows providers to avoid such overtime. Importantly, effective January 1, 2015, the DOL plans to narrow the current exemption so that it no longer applies to in-home service workers. This means that employers must meet the standards of the Rule for its non-skilled workers starting January 1, 2015. In-home services providers are in the throes of examining how to adjust and manage this workforce while still meeting patient needs and expectations.

To complicate matters, on October 9, 2014, the DOL indicated it will *delay enforcement* of the Rule until June 30, 2015 (the "Notice"). The DOL suggests this delayed enforcement is meant to assist the provider community with implementing changes in the Rule. In its commentary, the DOL suggests that non-enforcement means it will not bring actions against employers for alleged violations of the obligations resulting from these changes. Additionally, it will not investigate potential violations, supervise settlements for unpaid wages owed under the act or file suit in federal court to recover such wages. The DOL indicates that when it receives a complaint during this non-enforcement period, it will go to the employer and "work to educate the employer further on the requirements of the new regulation."

After the initial six-month non-enforcement period, the DOL intends to use "prosecutorial discretion" during the next six months (until December 31, 2015) when determining whether to prosecute alleged violations. The DOL states that it will make this determination on a case-by-case basis, and in making the assessment whether to prosecute, the DOL will consider the employer's efforts in order to implement the regulation, a state's efforts to make adjustments in order to implement the regulation and a state's efforts to bring its publicly funded home care programs into compliance. Based on these findings, it will determine whether or not prosecution is appropriate.

**CAUTION:** Despite the Notice, it is prudent for employers to meet the Rule's requirements as of January 1, 2015. Nothing in the Rule or Notice prevents a plaintiff's attorney from pursuing civil litigation against employers for violation of the Fair Labor Standards Act. The bottom line for providers is that home health aides, hospice aides and similar companionship workers will cease to be companionship workers on January 1, 2015. Here are a few things home health, hospice and private duty care industries should be doing now to prepare for the new year:

- Implement very specific scheduling processes and procedures to ensure caregivers are not working over 40 hours a week. This process should identify and alert the employer ahead of time when the 40-hour limit is approaching. Electronic tracking processes are ideal.
- Take steps now to be prepared to limit hours if/when necessary.
- Review existing policies on travel time, meal periods, weekend/night differentials, remote work, etc. These all must be addressed and accurately reflected when tracking caregivers' hours.
- Make sure policies relating to caregiver work hours are consistent and uniform.
- Recruit more caregivers now.

#### *Are Home Health Agency Conditions of Participation Really Changing?*

On October 8, 2014, CMS released a proposed rule that would revise the conditions of participation ("Proposed CoPs") that regulate home health agencies. CMS has not made major revisions to the CoPs since 1989. Notably, CMS did not follow through with proposed revisions in 1997, citing the significant volume of public comments and the rapidly changing nature of the home health industry at the time. Should CMS actually follow through with finalizing the Proposed CoPs, this will be the first major update in over 25 years. CMS claims that the proposed changes are based on principles of continuous and ongoing quality assessment and performance improvement, a fundamental approach that has already been implemented through the Conditions of Participation/Conditions of Coverage for end-stage renal disease suppliers, hospitals, hospices, transplant centers and organ procurement organizations.

Comments from the public were initially due December 8, 2014, but CMS recently pushed the acceptance date back until early January 2015. The home health industry will be watching very closely to see the fate of these Proposed CoPs unfold in the new year.

## 12. DOJ CRIMINAL DIVISION TO REVIEW ALL NEW FALSE CLAIMS ACT QUI TAM CASES

On September 17, 2014, the Criminal Division of the U.S. DOJ announced that it would review all new *qui tam* (i.e., whistleblower) complaints filed under the False Claims Act. While concurrent review of FCA cases by both the Civil and Criminal Divisions of DOJ is not unheard of, review of all cases by both divisions is new.

Under the new review procedure, the Civil Division of the DOJ will share *qui tam* cases with the Criminal Division as soon as they are filed. Experienced prosecutors in the Fraud Section will review the cases immediately to decide whether to open parallel criminal investigations. The DOJ Criminal Division's decision to devote more of its resources to *qui tam* cases could pose challenges to timely resolution of cases traditionally deemed to be only civil in nature. It is also consistent with the DOJ's prevailing view that civil monetary penalties under the civil provisions of the FCA often are not enough to deter wrongful conduct by provider entities and other organizations.

This development presents yet another reason for health care organizations to be vigilant in 2015 with enforcement of their compliance programs. Providers should focus on proper coding and billing practices and the maintenance of lawful relationships with referral sources.

## 13. FAILURE TO SUCCESSFULLY ATTEST TO "MEANINGFUL USE" MEANS PAYMENT ADJUSTMENTS FOR HOSPITALS BEGINNING OCTOBER 2014

The Medicare and Medicaid Electronic Health Care Record Incentive Program, commonly known as the "Meaningful Use Program," makes available financial incentives to providers to adopt, implement, upgrade and/or demonstrate meaningful use of Certified Electronic Health Record Technology ("CEHRT"). All eligible providers attesting to the Meaningful Use Program may be audited, per final rules published by the HHS on July 28, 2010 and September 4, 2012. Providers should plan ahead for a shift to compliance rather than incentives, especially with the Meaningful Use Program Audits ("Audits") that continue to play a large role in health care operations.

Providers should have an actionable compliance plan to navigate an Audit. If a provider fails an Audit, CMS allows an appeal; however, if the appeal fails, CMS expects the provider to refund the incentive payment for the applicable reporting period. A failed Audit also means that a provider did not successfully attest. **Beginning in October 2014 for eligible hospitals and 2015 for eligible professionals and critical access hospitals, failure to successfully attest can result in a payment adjustment to the provider's reimbursement.** Furthermore, a provider could be subject to penalties under other federal laws, including the Federal False Claims Act and the Health Insurance Portability and Accountability Act.

The Meaningful Use Programs and providers' implementation of CEHRT will continue to shape the future of health care management, improvement and delivery. Providers should beware the shift towards compliance to ensure that their policies and procedures are updated to successfully attest to Meaningful Use Program requirements.

## 14. CMS EXTENDS WAIVERS OF FEDERAL FRAUD AND ABUSE LAWS AS APPLIED TO ACOS

On October 17, 2014, CMS announced the extension of its November 2, 2011 interim final rule with comment period ("Waiver IFC") that established waivers of the Stark Law, the federal Anti-Kickback Statute and certain provisions of the Civil Monetary Penalties Law as these laws might apply to ACOs participating in the Medicare Shared Savings Program (the "Program"). The extension continues the effectiveness of these waivers until **November 2, 2015**, the date by which CMS must publish a final rule finalizing the waiver program. This means ACOs will continue to enjoy fraud and abuse protection as outlined in the Waiver IFC at least until November 2, 2015. Without the aforementioned extension, the Waiver IFC would have expired last month, leaving ACOs uncertain of their fraud and abuse exposure and less inclined to develop the creative care models envisioned by the Program. CMS believes the extension of the Waiver IFC will further its goal of "balanc[ing] effectively the need for ACO certainty, innovation and flexibility in the Program with protections for beneficiaries and the Medicare program."<sup>5</sup>

In addition to extending the Waiver IFC, CMS also requested comment from industry stakeholders on the following topics:

- How and to what extent ACOs are using the waivers;
- Whether the existing waivers serve the needs of ACOs and the Medicare program;
- Whether the waivers adequately protect the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services; and
- Whether there are new or changed considerations that should inform the development of additional notice and comment rulemaking.

More information can be found [here](#).

## **15. SURPRISE MEDICO-LEGAL ISSUE FOR 2014 - THE EBOLA EPIDEMIC**

2014 was the year of the largest Ebola epidemic in history. The epidemic severely affected Guinea, Liberia and Sierra Leone in West Africa. And while the Ebola threat appears to be decreasing in the U.S., health lawyers spent much of the fall educating themselves and their clients on the medico-legal ramifications of this highly infectious, deadly disease. According to a December 31, 2014 Ebola Situation Report published by the World Health Organization, there have been 20,206 reported cases of Ebola with 7,905 reported deaths. To date, there have been two imported cases in the U.S. including one death and two locally acquired cases in health care workers, both of whom recovered and were discharged from hospitals at the end of October. Heightened awareness, travel advisories, enhanced screening procedures, monitoring of persons potentially exposed to the virus, the provision of public health assistance to West Africa and massive advance preparation in hospitals continue to contribute to containment of the epidemic.

Following is a summary of some of the legal issues raised by the epidemic and our recommendations for front-line health care providers.

### *Public Health Preparedness - Generally*

Front-line health care providers (e.g., hospitals, health clinics, primary care physician offices, EMS agencies) should re-establish contacts with their local public health officers and emergency preparedness staff and review pandemic preparedness plans including procedures for increasing capacity for patients on isolation precautions. Hospitals should consider appointing an Ebola Site Manager who will be responsible for overseeing the care of Ebola patients. Hospitals should continue to run Ebola drills to help prepare personnel with a focus on donning/doffing personal protective equipment ("PPE"), performing routine care and procedures in PPE and post-care disinfection. These drills can be community-wide including EMS and the local public health department. An important legal aspect of a drill would be walking through the process of imposing quarantine on both willing and unwilling individuals. Providers should work with counsel to determine if the public health agency has the authority for immediate quarantine or if a court order is required.

### *CMS Memorandum on Ebola*

On October 10, 2014, CMS issued a memorandum with information for hospitals and critical access hospitals ("CAHs") concerning possible Ebola virus disease. In its memorandum, CMS strongly urges hospitals and CAHs to review and implement CDC guidance, particularly in their emergency and other outpatient departments, to allow for prompt identification and triage of patients who require further evaluation and to use CDC's preparedness checklist to ensure their readiness to handle Ebola patients. Failure to provide an appropriate medical screening examination could violate EMTALA obligations, and it is likely that CMS will consider compliance with CDC guidelines in determining whether a medical screening examination was "appropriate." On November 21, 2014, CMS issued a memorandum with additional guidance reminding providers that every emergency department is expected to have the capability to apply appropriate Ebola screening criteria when applicable and to immediately isolate individuals who meet screening criteria to be a potential Ebola case. In the event of any EMTALA complaints alleging inappropriate transfers or refusal to accept appropriate transfer, CMS will take into consideration the public health guidance in effect at the time.

### *Contract Considerations*

Providers should review medical waste disposal agreements to verify that the medical waste contractor is licensed and prepared to handle Ebola waste. Providers also should meet with their contractors to discuss the protocols for disposal of Ebola-contaminated waste in order to ensure that there is a clear understanding of the disposal process. Providers should review supply chain contracts to determine if they provide for immediate increases in deliveries of PPE and other supplies without delays for payment. Contracts may need to be modified to accommodate the demands of an epidemic.

### *HIPAA and Privacy*

The Ebola threat provides an opportunity for providers to remind staff of their obligations to protect the privacy of protected health information under HIPAA. Providers should forewarn employees with HIPAA refresher training that curiosity is not an acceptable reason to access medical record information and that violators will be disciplined. Review of the electronic health record ("EHR") audit trail for inappropriate access to the patient's EHR is a good enforcement tool. Privacy must be protected in the context of media inquiries as well. Providers should work with media relations to develop a communication plan to be used if a rule-out Ebola patient presents to the facility or

if there is any concern that a caregiver may have become infected.

## *Americans with Disabilities Act*

The ADA imposes limitations on making medical inquiries of employees and requires that any employee medical information obtained must be kept confidential. The ADA also limits an employer's right to exclude an individual from employment based on a disability unless it can demonstrate that the employee would pose a "direct threat." These and other concerns are addressed in a guidance document published several years ago by the U.S. Equal Employment Opportunity Commission entitled "Pandemic Preparedness In The Workplace And The Americans With Disabilities Act."

## *FMLA*

The Family and Medical Leave Act ("FMLA") protects employees who have a "serious health condition" or are "needed to care for" a family member who has a serious health condition. An employee who has no symptoms of disease likely would not have a serious health condition that would entitle the employee to FMLA leave.

## *NLRA and Constitutional Rights*

Hospitals should exercise caution before retaliating against employees who criticize the hospital or management for failing to provide safe working conditions. Private employers covered by the National Labor Relations Act ("NLRA") must be aware that this could be considered protected activity by employees and could also be a rallying point for union organizing. Although governmental employers are not covered by the NLRA, their employees enjoy free speech protections under the First Amendment when they speak out about matters of public concern. Therefore, governmental hospitals should exercise caution before disciplining employees for this reason.

## *Other Labor Concerns*

Hospitals should consider whether changes to shifts or staffing will be necessary to accommodate for the exhaustion and discomfort of wearing full-body PPE. If appropriate, hospitals should work with their union stewards regarding the needed changes in work practice.

## *Occupational Safety and Health Administration*

Hospitals should be prepared to deal with the possibility that some employees may refuse to treat certain patients or come to work at all. OSHA requires employers to provide their employees with working conditions that are free of known dangers. The NLRA has a similar provision that permits employees to cease work "in good faith because of abnormally dangerous conditions...at the place of employment." Retaliating against employees who reasonably believe they are in imminent danger could violate OSHA or the NLRA. In order to minimize these risks, hospitals should be sure to follow the most recent CDC and OSHA guidance regarding Ebola and be sure employees are kept well informed of the hospital's efforts in this regard.

For more detailed information, please see these articles:

- [Ebola Preparedness: Considerations for Clients and In-House Counsel;](#)
- [Ebola Preparedness - Detect, Protect and Respond: Next Steps for Health Care Providers and In-House Counsel;](#)
- [Ebola Preparedness - Take Steps Now to Ensure Health Care Workers and Hospitals Are Prepared to Care for Ebola Patients;](#) and
- [Ebola Preparedness - Important Takeaways from the October 21, 2014 Livestream Session.](#)

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Happy (Health Law) New Year from the health law attorneys of Hall Render. If you would like more information about any of these topics, please contact Eric Birdzell at 317.977.1558 or [hallrender@hallrender.com](mailto:hallrender@hallrender.com) to be put in touch with a Hall Render health law attorney.

Please visit the Hall Render Blog at [hallrender.com/resources/blog](http://hallrender.com/resources/blog) for more information on topics related to health care law.

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1The U.S. District Court for the District of Columbia dismissed this lawsuit (AHA, et al., v. Burwell, Civil Action No. 14-cv-851) on December



18, 2014.

2 Fresenius Med. Care Holdings, Inc. v. Tucker, 704 F.3d 935, 937 (11th Cir.2013); Accord U.S. ex rel. Osheroff v. Tenet Healthcare Corp., No. 09-22253-CIV, 2012 WL 2871264 (S.D.Fla. July 12, 2012); U.S. ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002-Orl-31DAB, 2012 WL921147 (M.D.Fla. Mar.19, 2012); Fresenius Med.Care Holdings, Inc. v. Francois, 832 F.Supp.2d 1364, 1367 (N.D.Fla.2011).

3 Linda Greenhouse, *Law in the Raw*, N.Y.TIMES, (Nov. 12, 2014) (last visited 12/16/2014)

4 See the Letter from then Secretary Kathleen Sebelius to Representative Jim McDermott of the State of Washington concluding that QHPs are not federal health care programs, found [here](#).

5 <http://www.gpo.gov/fdsys/pkg/FR-2014-10-17/pdf/2014-24663.pdf>