

November 2011

# BRACH EICHLER

# Health Law

# UPDATE



## FEDERAL UPDATE

### Final ACO Rules Released, Along with OIG, FTC, DOJ and IRS Guidance

The Centers for Medicare & Medicaid Services (CMS) released on October 20, 2011 its final rule for Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program. Responding to more than 1,300 public comments to the rule first proposed under the Affordable Care Act this past April, CMS made significant modifications intended to reduce the burden and costs for participating ACOs.

#### Highlights of Medicare Shared Savings Program Changes:

- Staggered start dates for early entries: April 1, 2012 and July 1, 2012
- Extended initial terms for early entries
- Risk and non-risk tracks still available, but the non-risk track does not require the sharing of losses in any year
- Beneficiaries are assigned using a preliminary prospective method, with a final reconciliation
- Beneficiaries are assigned by primary care services performed by specialists, PAs and NPs, in addition to those provided by primary care physicians
- Quality measures reduced from 65 measures in 5 domains to 33 measures in 4 domains
- Longer phase-in for quality measures: first year, pay for reporting; second and third year, pay for reporting and performance
- ACOs to share on first dollar saved once the minimum savings rate is achieved
- No withhold of shared savings
- Flexible approach to antitrust compliance

#### *In This Issue:*

**Final ACO Rules Released**

**OIG Issues Three Advisory Opinions**

**No Retroactive Liability Under NJ False Claims Act**

**Brach Eichler in the News**

**HIPAA Corner**

Coinciding with the Medicare Shared Savings Program final rule, CMS and the Department of Health & Human Services Office of Inspector General released an interim final rule concerning waivers for federal fraud and abuse laws and the Stark Law (the federal physician self-referral law). The interim final rule includes manageable requirements and offers protection for ACO participants during the period leading up to participation in the shared savings program, as well as waivers for participation in the program and for shared savings distributions, and waivers for relationships otherwise complying with a Stark Law exception and for beneficiary incentives.

Also released is the Federal Trade Commission and Department of Justice joint statement of antitrust enforcement policy for ACOs participating in the shared savings program, and the IRS fact sheet for tax-exempt organizations participating in the shared savings program. Both the joint statement and the fact sheet demonstrate greater flexibility for ACO participants. The antitrust statement, in particular, continues to include a 30% threshold and a complicated primary service area calculation for compliance with the safety zone, but it eliminates the previously required review of ACOs with a greater market share. Instead, the statement refers to the rule of reason analysis, and clinical and financial integration, first discussed in the 1996 statements of antitrust enforcement policy.

- CMS's Final Rule can be found at [http://www.ofr.gov/OFRUpload/OFRData/2011-27461\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf)
- The Federal Trade Commission and Department of Justice joint statement regarding antitrust enforcement policy can be found at <http://www.justice.gov/opa/pr/2011/October/11-at-1384.html>

*continued on page 2*

## BRACH EICHLER

- The CMS and the HHS OIG interim final rule concerning waivers for fraud and abuse and self-referral laws can be found at [http://www.ofr.gov/OFRUupload/OFRData/2011-27460\\_PI.pdf](http://www.ofr.gov/OFRUupload/OFRData/2011-27460_PI.pdf)
- The IRS fact sheet relating to tax-exempt organizations participating in ACOs can be found at <http://www.irs.gov/newsroom/article/0,,id=248490,00.html>

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### **OIG Disapproves of Management Services Arrangement Between Pathology Lab and Management Company Owned by Referring Physicians**

In a recent Advisory Opinion, No. 11-15, the U.S. Department of Health & Human Services Office of Inspector General (OIG) concluded that a proposed arrangement, whereby physician investors in a management company would provide laboratory management services on a percentage basis to a clinical laboratory to which they also refer patients, could potentially generate prohibited remuneration under the federal Anti-Kickback Statute.

Under the proposed arrangement, a company owned and managed by physicians would enter into a management services agreement with a pathology laboratory for a term of three years. The management company would furnish the pathology lab with the complete array of clinical laboratory pathology services for a fixed maximum number of hours each year, as well as utilities, furniture, fixtures and the exclusive use of laboratory space and equipment. The management company would also provide the pathology lab with marketing and billing services, as well as essential non-physician staff. In turn, the pathology laboratory would pay the management company a usage fee that would be calculated based on a percentage of the laboratory's income, fixed in advance for a term of 12 months, which generally would correspond to the volume of the laboratory's use of the management company's services, personnel and equipment. Furthermore, the physician owners/managers of the management company would likely have little or no background in the clinical laboratory services field.

The OIG noted the similarity this arrangement has with the questionable joint venture arrangements that have been the

subject of previous OIG guidance. Under this arrangement, the income of the physician-owned entity would vary with the volume or value of referrals from the physician investors. Because that aggregate usage fees paid by the management company would not be set in advance and would be calculated based on a percentage of the pathology laboratory's income, the OIG found that this fee structure would effectively link the physician investors' profit distributions to the laboratory business they send the pathology lab, posing considerable risk of overutilization of laboratory services, distorted medical decision-making and increased costs to federal health care programs.

As a result, the OIG concluded that the proposed arrangement appears to have no business purpose other than to permit the physician investors to profit from the business they generate for the pathology lab in the form of their laboratory specimen referrals. Based on these facts, the OIG concluded that the proposed arrangement would pose more than a minimal risk of fraud and abuse under the federal Anti-Kickback Statute and there was no safe harbor to bring this arrangement into compliance.

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### **Specialty Therapeutics Model – High Cost Drug Assistance Approved by OIG**

In a modification of an earlier advisory opinion, the U.S. Department of Health & Human Services Office of Inspector General (OIG) approved an arrangement that would allow an organization to subsidize the high cost to patients for specialty therapeutics prescribed for particular chronic or life-threatening diseases and enroll "participating pharmacies" to streamline the patient approval process. These drugs are especially burdensome for recipients because they generally require physician administration, self-administration by injection or infusion, special handling or storage, or significant patient education.

In 2007, the OIG approved the organization's arrangement to provide financial assistance to certain financially needy recipients, including federal health care program beneficiaries, with specified serious illnesses (OIG Advisory Opinion No. 07-18). The approved arrangement required that patients must have health insurance coverage for the

## BRACH EICHLER

particular disease, the insurance must cover the medication in issue, the medication must be used to treat the disease, and the patient must meet certain minimum income qualifications. The OIG has now amended the approval to include a subsidy for specialty therapeutics and a system of enrolling “participating pharmacies” because the OIG has determined that these changes do not increase the risk to the federal health care programs.

The concern is whether narrowly-defined disease categories could result in patients being steered to particular drugs based on the availability of the subsidy and encourage donors to contribute to the organization that have an interest in selling those products in violation of the Anti-Kickback Statute. However, the OIG was satisfied that the organization would retain decision-making authority about disease funds to be established, and each specialty therapeutic covered would be marketed by at least two different manufacturers. The OIG determined that programs using widely recognized clinical standards covering a range of available products present sufficiently low risk that donor contributions would improperly influence referrals or a patient’s selection of a service provider or supplier.

Further, the OIG did not object to pharmacies enrolling as “participating pharmacies,” in order to access an efficient processing system. The OIG determined that the arrangement was acceptable because it is open to any pharmacy, patients could use any pharmacy, and any pharmacy could still bill the organization directly.

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### OIG Looks Favorably on Limited Co-Management of Patients by Ophthalmologists and Optometrists

Last month, the U.S. Department of Health & Human Services Office of Inspector General (OIG) also issued Advisory Opinion 11-14, which permits ophthalmologists and optometrists to co-manage patients who undergo cataract surgery for the implanting of premium intraocular lenses (Premium IOLs). Although Medicare covers conventional intraocular lenses, it only partially covers Premium IOLs.

Under the proposed arrangement, after implanting Premium IOLs, the ophthalmology group would give the patient the option of obtaining follow-up care with an ophthalmologist or an optometrist. In this way, the ophthalmologists and optometrists would co-manage the cataract patient’s care. However, the optometrist may charge separately for his/her services to the extent not covered by Medicare. The ophthalmology group asked the OIG whether such a co-management arrangement would constitute remuneration in the form of an opportunity to earn a fee for follow-up care to a referral source, namely, the optometrists who may have referred the patient to the ophthalmologist for the cataract surgery in the first place.

The OIG concluded that the proposed co-management arrangement was permissible for the following reasons:

- There would be no written or unwritten agreements to co-manage patients. Moreover, patients would be informed that they could seek follow-up care from ophthalmologists or optometrists
- Patients would be informed that the optometrist may charge a separate fee for his/her services related to the Premium IOLs
- The increased costs associated with the Premium IOLs are not covered by Medicare

In issuing Advisory Opinion 11-14, the OIG cautioned that the opinion does not address other problematic co-management arrangements in which ophthalmologists and optometrists split a global fee. Accordingly, the Advisory Opinion is limited in scope to the specific facts of the proposed arrangement.

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### OIG Issues 2012 Work Plan

The U.S. Department of Health & Human Services Office of Inspector General (OIG) has released its 2012 Work Plan, which identifies various compliance and audit projects it will address during the fiscal year. The Work Plan includes projects planned in each of the Department of Health & Human Services’ major entities: CMS, the public health agencies, the Administrations for Children and Families, and the Administration on Aging. The Work Plan also includes information on projects related to issues that affect multiple programs, such as state and local government use of federal

funds. The Work Plan addresses Medicare Parts A, B, C and D; Medicaid reviews; legal and investigative initiatives and public health and human services reviews.

Some of the key hospital initiatives include:

- Reviewing hospitals' controls for ensuring the accuracy and validity of data related to quality of care that is submitted to CMS
- Reviewing Medicare payments to hospitals to determine compliance with selected (not specified) billing requirements
- Interviewing/surveying hospital leadership and compliance officers about their compliance programs

The Work Plan contains the following key initiatives for physicians:

- Reviewing the extent to which providers comply with assignment rules and determining to what extent beneficiaries are billed in excess of amounts allowed by Medicare
- Reviewing physician billing for incident-to services to determine whether payment for such services had a higher error rate than non-incident-to services

Some key initiatives for long-term care include:

- Reviewing Medicare- and Medicaid-certified nursing homes' implementation of the Affordable Care Act requirement that nursing homes have compliance and ethics programs that include eight specific components on or after 2013
- Reviewing CMS' and States' use of enforcement measures to determine their effect on the quality of care beneficiaries receive in poorly performing nursing homes

Some key initiatives affecting home health agencies (HHA) include:

- Reviewing HHA claims not accompanied with OASIS data, and claims inconsistent with OASIS data
- Reviewing HHAs to identify those agencies exhibiting "questionable billing," which the OIG defines as claims that exhibit "certain characteristics that may indicate potential fraud"
- Reviewing home health claims to determine the degree to which such claims meet Medicare coverage requirements

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## STATE UPDATE

### **Court Makes Clear That NJ False Claims Act Does Not Apply Retroactively**

The New Jersey Appellate Division recently held that the New Jersey False Claims Act does not apply retroactively to alleged false claims that were submitted before March 13, 2008, the effective date of the Act.

In the case, *State v. Corr. Med. Serv., Inc.*, from 1996 through March 31, 2005, Correctional Dental Associates (CDA) provided dental services to inmates of New Jersey's prisons. In 2005, the contract was awarded to Correctional Medical Services (CMS) and AllCare Dental Group, for the dental portion of inmate care. In 2005, Leslie Hayling, the owner of CDA, commenced an investigation of CMS and AllCare, which led him to conclude that AllCare was submitting false claims for payment under the dental portion of the contract.

On August 25, 2008, Hayling filed a *qui tam* suit against AllCare for the claims AllCare submitted from April 1, 2005 through March 31, 2007. In a *qui tam* suit, the person bringing the action, known as the relator, is awarded a share of the proceeds of a successful action. Following service, the defendants moved to dismiss the complaint because the claims were submitted before the effective date of the Act.

The court determined that the Act is not retroactively applicable to conduct occurring prior to its effective date. The court applied accepted rules of statutory construction and found that any exceptions to the rule that the application of new laws are to be applied prospectively only did not apply in this case because the statute clearly set forth an effective date of March 13, 2008. The court additionally determined that there was no requirement to apply the statute retroactively to make the statute workable, to give it the most sensible interpretation, or for any of the other reasons that were suggested to the court.

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## **DHSS Implements Mandatory Universal Transfer Form**

New Jersey regulations requiring the mandatory use of the New Jersey Department of Health and Senior Services (DHSS) Universal Transfer Form (UTF) (N.J.A.C. 8:43E-13) went into effect on October 30, 2011. The UTF is to be completed and sent by all licensed health care facilities with a patient, whenever a patient is transferred to another licensed healthcare facility or program.

DHSS instituted use of the UTF to ensure that accurate communication of pertinent, accurate clinical patient care information is conveyed at the time of transfer of a patient between health care facilities or programs. The UTF is meant to convey patient information required under federal regulations as well as specific facts that a physician or nurse may need to immediately begin caring for a patient when the patient arrives at a new facility or program.

The UTF was designed, tested and refined over a three-year period by a special task force comprised of medical professionals, DHSS, health care associations and Rutgers University. In response to comments DHSS received on the proposed use of the UTF, DHSS developed instructions for the UTF, which includes explanations of the acronyms and phrases used on the UTF. The UTF and the instructions are available at <http://web.doh.state.nj.us/apps2/form>.

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## **Brach Eichler In The News**

Brach Eichler Managing Member John Fanburg, who also chairs the health care practice group, is one of six individuals in New Jersey who have been selected as finalists in the Executive of the Year category in the 2011 Business of the Year awards program presented by *NJBIZ*, New Jersey's premier business news publication. The Business of the Year awards program celebrates New Jersey's most dynamic businesses and business leaders who share a commitment to professional excellence, business growth and the community.

Brach Eichler was honored by the Bergen Volunteer Medical Initiative, receiving the Corporate Spirit of Giving Award.

Health care practice group member Kevin Lastorino is speaking on "Understanding Accountable Care Organizations (ACOs)" to the members of the Hunterdon County Medical Society at its monthly meeting on November 15.

Health care practice group member Mark Manigan spoke on "Hot Topics in Trenton/Business Trends" to the New Jersey Orthopaedic Society's fall meeting. On October 27, Mr. Manigan also spoke at the Council on State Public Affairs' State of the State 2011 Conference on Revitalizing Our Economy. The topic: "Healthcare in New Jersey: Who Will Pay the Bill?"

Last month, John Fanburg presented a "Legal Update" at the 61st Annual Seminar & Annual Meeting of the New Jersey Society of Pathologists.

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## **HIPAA CORNER**

On September 14, 2011, Science Applications International Corporation (SAIC), in its role as a business associate and/or subcontractor for TRICARE, the military health plan, reported a data breach involving personal information impacting an estimated 4.9 million military clinic and hospital patients. According to the press statement issued by TRICARE, the information was contained on backup tapes from an electronic health record used in the military health system to capture patient data from 1992 through September 7, 2011, and included Social Security numbers, addresses and phone numbers, and some personal health data such as clinical notes, laboratory tests and prescriptions. No financial data, such as credit card or bank account information, was contained on the backup tapes.

In its press statement, TRICARE advised that the risk of harm to patients was judged to be low despite the data elements involved, since retrieving the data on the tapes would have required knowledge of and access to specific hardware and software and knowledge of the system and data structure. Notwithstanding the determination that the risk of harm was low, TRICARE notified beneficiaries affected by the breach due to Department of Defense requirements and the totality of the circumstances.

## BRACH EICHLER

Not only should this incident remind covered health care providers of the importance of their breach notification policies and procedures, but also of their relationships with their business associates. Business associate agreements should ensure that business associates are required to notify the covered provider of a security breach promptly so that the provider can determine next steps, including whether or not to notify affected individuals. By way of background, the Health Information Technology for Economic and Clinical Health Act's breach notification rule requires that covered health care providers inform their patients when there

has been a breach of their protected health information. The term "breach" is broadly defined as the unauthorized acquisition, access, use or disclosure of protected health information in a manner not permitted by the HIPAA privacy rule which compromises the security or privacy of such information.

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