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A newsletter on the current legal issues facing today's health care industry

Second Quarter 2011

Industry Pressure Points May Shape Final ACO Rule

By William H. Maruca

The Obama administration's proposed rule for Accountable Care Organizations has taken a beating from critics in recent weeks, but as the June 6 comment deadline passes and regulators react, we will see if one of the centerpieces of health care reform can be retooled to attract key players.

As embattled CMS Administrator Donald Berwick, M.D., stated in an optimistic May 17 editorial titled "We Can Have It All," the Affordable Care Act (ACA) provides a variety of tools for improvement of the health care system:

> "One of those important new tools is the so-called Accountable Care Organization. The idea of the ACO is to encourage and support physicians, hospitals and other providers to lower costs by providing better quality care, and to reward them for success by allowing them to share in the resulting savings. ACOs are part of an important agenda of change: to shift American health care from a system based on the volume of care (the more you do, the more you get paid) to one based on the results of care (the better you do for patients, the more you get paid)."

Much of the pushback has focused on the perceived disconnect between the cost and complexity of setting up an ACO compared to the amount and timing of the potential rewards. In May, CMS responded to some of the concerns by establishing an Advance Payment Initiative along with offering other options and resources.[1]

Additionally, health care organizations and interest groups have expressed reservations about the absence of an upside-only shared savings model, the number and complexity of the 65 proposed quality measures, the uncertainty arising out of CMS' chosen retrospective patient attribution method and the antitrust obstacles remaining under the Justice Department/Federal Trade Commission proposal.

Among the high-profile players who have raised qualms about the program in its proposed form are the Mayo Clinic, the Cleveland Clinic, Sutter Health, Marshfield Clinic and the 10 members of the CMS Physician Group Practice demonstration project. It is entirely possible these players are holding out as a strategy to obtain more favorable terms from the administration in the final rules.

Political opposition is solidifying as well, particularly as the constitutional challenges to the ACA are not expected to prevail according to many experts. A group of seven Republican senators, led by Tom Coburn of Oklahoma, wrote[2] to urge HHS Secretary Kathleen Sebelius and Dr. Berwick to scrap the proposed rule and start over, although they did not offer any specifics for a revamped rule.

Costs of Implementation

The American Hospital Association (AHA) released a report claiming CMS had significantly underestimated ACO startup costs.[3] The AHA's study found the necessary elements to successfully manage the care of a defined population from launch through the first year of operation would range from $11.6 million for a 200-bed, single hospital system, to $26.1 million for a 1,200-bed, five-hospital system, as opposed to CMS' estimate of $1.8 million.

The AHA engaged the McManis Consulting firm, which evaluated a number of existing health systems that performed functions similar to those required of ACOs. The McManis study identified 23 separate capabilities in four categories: network development and management; care coordination, quality improvement and utilization management; clinical information systems; and data analytics.

In a May 13 letter[4] to CMS, the AHA urged the agency to adjust the shared savings rate in recognition of the higher costs in order to encourage and enable participation. The funding gap and its related timing issues have not escaped notice at CMS.

The Center for Medicare and Medicaid Innovation announced[5] on May 17 it is considering an Advance Payment Initiative for those ACOs entering the Medicare Shared Savings Program to test whether and how pre-paying a portion of future shared savings could increase participation

In This Issue:

1 http://www.healthcare.gov/news/factsheets/accountablecare05172011a.html
2 http://coburn.senate.gov/public//index.cfm?a=Files.Serve&File_id=3dc75d6b-0099-4c21-b2d9-dbd83aa3cc91
3 http://www.aha.org/aha/press-release/2011/110513-pr-aco.html
4 http://www.aha.org/aha/letter/2011/110513-let-fishman-berwick-aco-case-studies.pdf
5 http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment/

in the Medicare Shared Savings Program. The plan would allow eligible ACOs to receive an advance on their anticipated shared savings to be applied to build care coordination capabilities and meet other organizational criteria. CMS is accepting comments through June 17 on this initiative.

Antitrust Obstacles

Michael D. Maves, M.D., MBA, CEO of the American Medical Association (AMA), has raised a number of concerns about the proposed antitrust policy in a May 26 letter[6] to the Federal Trade Commission.

The AMA contends the joint FTC-Department of Justice policy favors hospital-dominated ACOs over physician-led ACOs and will lead to even more practice acquisitions and consolidation in the market. Additionally, the AMA argues the proposed policy will result in "false positives" for market power and would discourage many potential arrangements that would otherwise be pro-competitive and be able to deliver the desired quality and savings.

The proposed enforcement policy divided ACOs into three tiers for antitrust purposes. For an ACO to fall within a "safety zone," independent ACO participants (e.g., physician group practices) that provide the same service must have a combined share of 30 percent or less of each such common service in each participant's Primary Service Area (PSA), wherever two or more ACO participants provide that service to patients from that PSA.

The PSA for each service is defined as the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75 percent of its patients for that service. Those ACOs between 30 and 50 percent may request an optional review by the agencies, and those who exceed 50 percent will be required to obtain a review. The AMA contends the agencies' methodology will distort the results and assign most applicants into the highest-risk antitrust category.

Pioneer ACO Model

Recognizing that some well-integrated entities may be ready to accept more risk and responsibility from the start, CMS announced a Pioneer ACO model[7] as an alternative to the shared savings program on March 17. This program resembles an RFP-style solicitation. Each ACO must manage a minimum of 15,000 beneficiaries (5,000 in rural areas), who would be identified prospectively. A retrospective alignment may be selected by negotiation with CMS, if desired. Pioneer status is limited to 30 ACOs. Letters of intent are required by June 10 and completed applications by June 18.

The core payment arrangement will be similar to the shared savings program with greater levels of upside gain and downside risk, but a second-tier payment system is also anticipated. A 35-page Request for Application[8] has been published, and it may provide some indication of what the Shared Services ACO application may look like after the final rule is published.

Armchair Predictions

From my perspective, I anticipate the White House will exert pressure on the various regulatory agencies to tweak the rules in a manner that entices enough entities to participate so that the administration can describe the program as a successful step toward bending the cost curve and ensuring quality care.

Various stakeholders may seize the opportunity to shape the shared savings program to their own advantage. I can see the percentage of cost savings being increased, the antitrust barriers being streamlined and a possible no-downside option being added, among other changes. The final rules will determine whether the ACO concept will fly in the short run and spread to the private insurance market in the mid to long term.

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6 http://www.ama-assn.org/resources/doc/washington/aco-antitrust-reform-proposal-comment-letter.pdf
7 http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco/
8 http://innovations.cms.gov/wp-content/uploads/2011/05/Pioneer-ACO-RFA.pdf

ACOs: Getting More for Less?

The NJ Medicaid ACO Model Seeks to Save Taxpayer Dollars While Improving Health Care

By Elizabeth G. Litten

There's a new model on the health care scene: the accountable care organization, or ACO. The premise of an ACO is that aligning the interests of otherwise separately operating, often competing and frustratingly noncommunicating health care providers, payers and patients will lower costs while improving access to and quality of health care. If accountability is truly shared among the various parts of the system, then opposing or disjointed facets of the system will create ways to work together to produce the best results.

While it is tempting to dismiss the ACO model as simply renamed physician hospital organizations (PHOs), independent practice associations (IPAs) or closed-panel HMOs of the past, these prior attempts to revise how health care was delivered or reimbursed focused on aligning discrete segments of the health care system. They rarely, if ever, rewarded component parts of the model for the quality and efficiency achieved by the whole. These models pre-dated the health information technology systems we have today and were developed in an era when volume was viewed as a rational basis for reimbursement.

The interconnected, data-driven, results-oriented health care world of today makes a volume-based payment system seem archaic and ineffective. Moreover, because

the consumer cost of health care (as measured by resource use or volume) does not correlate to its quality, figuring out how to spend health care dollars more wisely may actually result in keeping us healthier.[1]

The Patient Protection and Affordable Care Act, P.L. 111-148 (PPACA or the Affordable Care Act) as amended by the Health Care and Education Reconciliation Act, P.L. 111-152, grapples with complex health care cost and quality issues in a wide variety of ways, many of which have been challenged. The Centers for Medicare and Medicaid Services (CMS) described the Medicare ACO model as set forth in PPACA as follows:

> The Affordable Care Act seeks to improve the quality of health care services and to lower health care costs by encouraging providers to create integrated health care delivery systems. One important delivery system reform is the Medicare Shared Savings Program under section 3022 of the Affordable Care Act, which promotes the formation and operation of accountable care organizations (ACOs).[2]

CMS explains that section 3022 allows groups of providers to "work together to manage and coordinate care for Medicare" beneficiaries through an ACO, which can receive payments from Medicare for shared savings if certain quality performance standards are met. According to CMS, the model creates a structure for collaboration among providers to incentivize higher-quality, lower-cost medical care. PPACA outlined the skeletal structure of a Medicare ACO, and CMS recently proposed regulations,[3] putting 427 pages of flesh on the Medicare ACO body.

However, it is likely that individual ACOs — whether created as Medicare ACOs or "commercial" ACOs formed in collaboration with non-government third-party payers (such as carriers and self-funded employer plans) — will contain features unique to that ACO's participants and patient population. A common feature of a successful ACO will be its ability to connect and synchronize the interests of the providers, payer(s) and patients. Even a perfectly conceived, carefully constructed, legally impervious ACO will fail to achieve its "patient protection" (or health care quality) and "affordability" goals if its parts fail to work in concert.

The New Jersey Medicaid ACO model was conceived as a way to achieve and reward high-quality, appropriately accessible and affordable patient care in communities in which these traits are most often and obviously lacking. Like many states, New Jersey faces a significant budget crisis. The affordability of the existing Medicaid program, let alone any expansions to the program, is a key concern to the governor, legislators and New Jersey taxpayers. Medicaid beneficiaries often live in poor areas, have poor access to primary care (and fewer resources to find or obtain specialty care), and have greater dependence on local emergency rooms.

The New Jersey Medicaid ACO Demonstration Project (the Project) was introduced as S2443 by Senator Joseph F. Vitale on Nov. 8, 2010. As introduced, the Project shares elements of the Medicare Shared Savings Program outlined in PPACA but is applicable specifically to beneficiaries whose care is paid for by the New Jersey Medicaid fee-for-service (FFS) program and who reside within the region covered by the approved (or certified, as described in the bill), regional Medicaid ACO.

The Project would not alter the way in which Medicaid claims are currently paid. Rather, it would allow an additional payment to providers participating in the Medicaid ACO to the extent savings are achieved (and from the savings realized, not from additional or new revenue required to fund the Project) as a result of improvements in access to needed services, achievement of quality standards and coordination and information-sharing among the various participating providers. The Medicaid ACO would "sit on top" of the existing care delivery and payment system and function as an invisible (to the patient), cohesive layer.

The Project would permit voluntary participation by a Medicaid managed care organization (MCO). The Medicaid MCO would function in a role similar to that of Medicaid FFS, in that its participation would not alter the way in which the MCO currently reimburses providers for services rendered to its members. In addition, the MCO would continue to receive premium payments from Medicaid and operate in accordance with its Medicaid contract. As with the Medicaid FFS program, if savings result from the improvements instituted by the Medicaid ACO, the Medicaid MCO would share those savings with the participating providers.

The Medicaid ACO model was not developed in a vacuum. In the City of Camden, one of the most impoverished cities in the United States, local health care providers worked for the past nine years to build a nonprofit, ACO-type coalition, the Camden Coalition of Healthcare Providers (CCHP), committed to improving the quality, capacity and accessibility of the local health care delivery system. CCHP's efforts began with the development of a citywide health database that collected claims data from the three acute care hospitals serving the city. The data collected demonstrated the stark reality that Camden residents lacked adequate access to primary care and were using emergency rooms or hospitals at twice the national rate. In a single year, CCHP found that 50 percent of the city's residents used an emergency room or hospital; one resident used emergency room or hospital services 113 times in a year. CCHP's claims data analysis also revealed the vast majority of these visits were for health needs better addressed or prevented by visits to primary care providers.

The top 10 diagnoses associated with Camden residents' emergency room visits from 2002 through 2007 were due to health conditions better treated in a primary care setting. During the 2002-2007 period, there were 317,791 visits to one of Camden's three emergency rooms. Of these visits, 12,549 were for a diagnosis of an acute upper respiratory infection not otherwise specified (head cold); 7,638 were for a diagnosis of middle ear infection; 7,577 were for a diagnosis of an unspecified virus; 6,195 were for a diagnosis of a sore

[1] See, e.g., Baicker and Chandra, "Medicare Spending, the Physician Workforce and Beneficiaries' Quality of Care," *Health Affairs* (Millwood), April 7, 2004, http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.184.

[2] http://www.federalregister.gov/articles/2010/11/17/2010-28996/medicare-program

[3] http://www.cms.gov/sharedsavingsprogram

throat; and 5,393 were for a diagnosis of asthma. The remaining diagnoses on the "top 10" list related to ailments that included fever, chest pain and headache.

The most frequent utilizers of hospital and emergency rooms during this time period, consisting of 1,035 Camden residents, each visited the emergency room or hospital between 24 and 324 times. CCHP identified total hospital charges associated with these patients of $375 million, with actual payments of $46 million (not including charity care reimbursement). The $46 million payment, if redirected to preventative and primary care services, could fund 50 primary care physicians or 100 advanced practice nurses. It would also eliminate an estimated (given that charges do not equate to actual costs) hospital revenue shortfall of $300 million.

CCHP's efforts to reduce emergency room usage began by transforming local primary care offices into patient-centered medical homes using multidisciplinary care teams to target the "top utilizers;" electronic health records and a local health information exchange accessible by all local providers; open-access scheduling; and patient registries. CCHP's success in addressing the health care needs of Camden residents presented a compelling case for creating an ACO model specifically designed to serve a defined group of patients. While not every Medicaid beneficiary resides in a city that resembles Camden, the Medicaid ACO model injects a framework and funding source for collaboration and coordination where it is likely to be most lacking and where targeted improvements are most likely to produce relatively fast, measurable and positive results.

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Certification Requirements for Health Information Technology: A 2011 Primer for Providers

By Elizabeth G. Litten

Weeding through the thicket of health information technology (HIT)-related regulations promulgated by the U.S. Department of Health and Human Services (HHS) over the past couple of years is not a task for the distracted or sleep-deprived. Only the most intrepid and focused readers will emerge with the realization that regulations issued by the Centers for Medicare & Medicaid Services (CMS) within HHS pertaining to meaningful use of electronic health record (EHR) technology are distinct from, albeit related to, regulations issued by the Office of the National Coordinator for Health Information Technology (ONC) within HHS pertaining to certification of EHR. In fact, as explained by the ONC in the "Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Information Technology" published July 28, 2010 ("Initial Certification Rule"),[1] a number of the nearly 400 timely comments it received on the Interim Final Rule with request for comments[2] were really intended for CMS and pertained to the CMS meaningful use regulations:

> [D]ue to the simultaneous publication and topical similarity of the notice of proposed rulemaking for meaningful use Stage 1, commenters inadvertently submitted comments to our regulation docket … instead of … [CMS] and vice versa. Recognizing this oversight, CMS and ONC shared misplaced comments between the offices and we included within our review all comments that could reasonably be identified as comments on the Initial Certification Rule.[3]

The interplay between meaningful use of EHR and certification of HIT undoubtedly lends to the confusion, as do the multiple implementation phases and lengthy, technical regulations associated with both meaningful use and certification. The "simultaneous publication" of ONC and CMS rules dated last summer certainly did not help to clear the dense thicket of HIT and EHR-related information.

Many health care providers have focused on meeting the requirements for "meaningful use" of EHR. On the same date of ONC's Initial Certification Rule publication, CMS published a Final Rule[4] setting forth requirements for the incentive payments authorized by the American Recovery and Reinvestment Act of 2009[5] (ARRA) (EHR Incentive Program Final Rule). The EHR Incentive Program Final Rule and its preamble, consisting of more than 250 single-spaced, mini-font pages, describe the way in which providers must develop and meaningfully use EHRs in order to qualify for the Medicare and Medicaid payment incentives. Under the Medicare EHR incentive program, eligible providers must adopt and meaningfully use certified EHR technology before receiving incentive payments. Under the Medicaid EHR incentive program, eligible providers may receive incentive payments if they adopt, implement or upgrade to certified EHR technology within their first year of participation in the incentive program.

Providers looking to qualify EHR for the Anti-Kickback Statute EHR safe harbor[6] and/or the Stark physician self-referral prohibition exception[7] must use HIT "deemed" by the Secretary of HHS to be "interoperable." HIT is "deemed to be

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1 75 Fed. Reg. 44590(July 28, 2010). See also 75 Fed. Reg. 62,686 (Oct. 13, 2010)(revisions to Initial Certification Rule).
2 75 Fed. Reg. 2014 (Jan. 13, 2010).
3 75 Fed. Reg. at 44591.
4 75 Fed. Reg. 44314 (July 28, 2010) See also 75 Fed. Reg. 81885 (Dec. 29,2010)(final rule correcting amendment to EHR Incentive Program Final Rule).
5 Pub. L. 111-5 (2009).
6 42 C.FR. 1001.952(y).
7 42 C.F R. 411.357(w).

interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient."[8] Thus, providers seeking Medicare and/or Medicaid incentive payments, as well as providers seeking protection for EHR technology donations under the Anti-Kickback Statute or Stark law, must be sure the EHR technology is certified.

Background on the Certification Rule

On June 24, 2010, the ONC published a final rule establishing a temporary certification program for HIT.[9] On January 7, 2011, the ONC published a "Final Rule for the Establishment of the Permanent Certification Program for Health Information Technology" (Final Certification Rule).[10] As explained in its news release issued January 3, 2011, the Final Certification Rule was developed to enhance "the comprehensiveness, transparency, reliability, and efficiency of the current processes used in the certification" of EHR technology.[11] In short, the ONC has outlined a process by which HIT will become "permanently" certified:

- The ONC will request that the National Institute of Standards and Technology (NIST), through its National Voluntary Laboratory Accreditation Program (NVLAP), develop a laboratory accreditation program for organizations to be accredited to test HIT for permanent certification.
- Once NIST/NVLAP has developed accreditation standards, the ONC will select an Approved Accreditor (ONC-AA). The ONC-AA will then approve applicants seeking designation as Authorized Certification Bodies (ONC-ACBs) or Authorized Certification and Testing Bodies (ONC-ACTBs).
- ONC-ACB/ACTBs must demonstrate to ONC-AA its competency and ability to test and and/or certify Complete EHRs, EHR Modules and/or other types of HIT as specified by the Secretary of HHS.
- After becoming an ONC-ACB/ACTB, an organization may test and/or certify the product of an HIT vendor or developer as constituting an "EHR Module" or a "Complete EHR" (i.e., an EHR that meets, at a minimum, all of the applicable certification criteria required by the Secretary as per regulatory requirements set forth in the Initial Certification Rule).
- Following certification of the HIT pursuant to the process described above, the ONC-ACB/ACTB will provide the ONC, no less frequently than weekly, a current list of Complete EHRs and EHR Modules that have been certified. The ONC will post the information on its web site in its Certified HIT Products List (CHPL).[12]

Buyer Beware Caveats

The process, while detailed, is relatively straightforward and contains information more immediately or directly relevant to HIT developers and vendors. However, there are a few "buyer beware" caveats lurking amidst the Interim Final Rule and the Permanent Certification Rule provisions for providers purchasing new or upgraded HIT systems.

First, despite the "Permanent Certification Rule" label, the process set forth in the rule makes it clear that certification is not necessarily permanent, as it is only valid as long as the certification criteria have not been modified. "In other words, if the applicable certification criteria have been altered or changed, then an eligible professional or eligible hospital can no longer represent that a certified Complete EHR or a combination of certified EHR Modules continues to constitute Certified EHR Technology based on the certifications that were previously issued."[13] The ONC explains that it expects the requirements for meaningful use will be adjusted every two years, and that the Secretary will then adopt certification criteria every two years to correlate with the changes to the meaningful use requirements. So, if a Complete EHR was certified in 2010 to meet criteria for the 2011 and 2012 payment years, it must be certified again in 2012 to meet the 2013 and 2014 criteria. Fortunately, though, Complete EHRs and EHR Modules that were certified under temporary certification criteria adopted for the 2011-2012 payment years will not require recertification simply because the Final Certification Rule has been promulgated.

Purchasers should also beware of buying components of a Complete EHR and expecting the component to qualify as an EHR Module. As explained by the ONC in a frequently asked question (FAQ) response, "[s]tand-alone, separate components of a certified Complete EHR do not derive their own separate certified status based solely on the fact that they were included as part of the Complete EHR when it was tested and certified."[14] Purchasers should make sure the EHR vendor has received specific EHR Module certification for each component of the Complete EHR if the purchaser wants to buy only certain component parts (perhaps at a cost that is less than the cost of purchasing the Complete EHR).

Similarly, purchasers using a combination of EHR Modules will need "to ensure that a combination of EHR Modules properly work together to meet all of the required capabilities necessary" to meet required privacy and security requirements. The Permanent Certification Rule requires EHR Modules to be certified to all privacy and security certification criteria adopted by HHS, unless the Module(s) is presented for certification as a pre-coordinated, integrated bundle and one or more of the constituent Modules is "demonstrably responsible" for providing all of the privacy and security capabilities of the entire bundle, or it is presented for certification and the presenter can show that a privacy and security certification criterion is inapplicable or that it would be technically infeasible to certify the Module in accordance with the criterion.[15] A purchaser of bundled modules should, therefore, make sure it plans to use the entire bundle or that it fully

[8] *Id.*
[9] 75 Fed. Reg. 36,158 (June 24, 2010).
[10] 76 Fed. Reg. 1262 (Jan. 7, 2011).
[11] http://www.hhs.gov/news/press/2011pres/01/20110103a.html
[12] http://onc-chpl.force.com/ehrcert
[13] 76 Fed. Reg. at 1302.
[14] http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163
[15] 76 Fed. Reg. at 1329.

understands potential limits associated with use of a single Module or portion of the bundle. Since privacy and security capabilities are a key feature of a provider's HIT (and the absence of these capabilities can result in breaches and problems far beyond those associated with the failure to qualify for a meaningful use incentive payment), the provider should carefully review these features in the context of how it intends to adopt and use EHR Modules.

Health care attorneys advising HIT-purchasing or using clients would be wise to focus on the representations and warranties included in vendor contracts, make sure their clients have a complete understanding of the purpose for and way in which the HIT will be used, and should have at least a general understanding of the symbiotic, but distinct, relationship between HIT certification and meaningful use.

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Hospitals and Health Care Providers Beware: You May Be Subject to Federal Affirmative Action and Equal Employment Opportunity Hiring Requirements and Not Even Know It!

By Kenneth A. Rosenberg and Todd A. Palo

Recently, the U.S. Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) has been notifying hospitals and other health care providers that they are "federal contractors" who are subject to OFCCP jurisdiction based on their participation in TRICARE or provision of services to TRICARE beneficiaries. The notice further advises that due to the hospital's or health care provider's "federal contractor" status, it must provide the OFCCP with an Affirmative Action Plan and supporting documentation or risk being audited and fined. Predictably, this notice has surprised many hospitals/health care providers because they never entered into a federal contract regarding TRICARE and thus never suspected they were subject to the OFCCP's jurisdiction.[1]

However, an entity can be deemed a "federal contractor" not only for having a direct arrangement or contract with the U.S. government, but also where it enters into a subcontract with a U.S. government contractor. Pursuant to Executive Order 11246 and related statutes, a "subcontract" is defined as:

> any agreement or arrangement between a federal contractor and any person, not in an employer/employee relationship: (1) for the purchase, sale or use of personal property or nonpersonal services which, in whole or in part, is necessary to the performance of a contract, or (2) under which any portion of the federal contractor's obligation under the contract is performed, undertaken or assumed. See 41 CFR §§ 60-1.3, 60-250.2(1), 60-300.2, 60-741.2(1).

As such, a hospital or health care provider can be subject to the OFCCP's jurisdiction where it enters into a written or unwritten agreement or arrangement with a "federal contractor" to: (1) provide personal property or nonpersonal services that, in whole or part, is necessary to the performance of the federal contractor's contract with the government or (2) perform, undertake or assume any portion of the contractor's obligations of the federal contract.

Additionally, a "subcontractor relationship" can exist where an entity contracts with a covered subcontractor to provide supplies or services necessary to the performance of the prime contract or to fulfill an element of the prime contract. See OFCCP Order No. 293 ADM Notice/Jur., at 5 (Dec. 16, 2010). Either way, another link in the "subcontractor relationship" chain is created resulting in both entities being deemed "subcontractors" and thus subject to OFCCP jurisdiction. Hence, if a covered subcontractor enters into contracts with multiple companies, the OFCCP has jurisdiction over all of these "subcontractors," provided the subcontracts are related to the execution of the prime contract.

Pursuant to OFCCP policy, whether or not an agreement or other arrangement is labeled a "subcontract" by the parties is irrelevant to the OFCCP's "subcontractor relationship" analysis. *Id.* at 4. This is because the OFCCP has stated its regulations rather than the parties' contractual language governs this determination. Thus, a contractor's OFCCP obligations cannot be altered, limited or defeated by the inclusion in a contract or arrangement of provisions contrary to such obligations. *Id.*

The OFCCP has recently applied the foregoing principles to assert its

[1] The OFCCP is the governmental agency responsible for enforcing the federal affirmative action and equal opportunity employment obligations mandated by: (1) Executive Order 11246, (2) Section 503 of the Rehabilitation Act of 1973 and (3) the Vietnam Era Veterans' Readjustment Assistance Act of 1974. See Exec. Order No. 11,246, 3 F.F.R.330 (1964-1965), reprinted in 42 U.S.C. § 2000e app. at 28-31 (1982); The Rehabilitation Act of 1973, Pub. L. No. 93-112, 87 Stat. 355 (codified as amended at 29 U.S.C. § 793 (1988)); Vietnam Era Veterans' Readjustment Assistance Act of 1974, 38 U.S.C. §§ 4211-4215 (2002), as amended.

jurisdiction over hospitals that participate in or provide services to federal health care programs such as TRICARE and the Federal Employees Health Benefit Plan (FEHBP).

In *OFCCP v. UPMC Braddock, UPMC McKeesport, UPMC Southside*, ARB Case No. 08-048 (May 29, 2009),[2] the Department of Labor's Administrative Review Board (ARB) found that three hospitals were subject to OFCCP jurisdiction even though they did not have a contract or arrangement with the federal government. The ARB reached this conclusion because it found the hospitals had entered into a contract with UPMC Health Plan, an HMO, to provide medical products and services to the U.S. Office of Personnel Management's (OPM) employees who had Federal Employee Health Benefit Plan (FEHBP) coverage. The UPMC Health Plan, in turn, had contracted with the OPM to provide medical services and products to their employees through the FEHBP. As such, the ARB found the hospitals were subcontractors of the UPMC Plan because it was enabling the UPMC Health Plan to meet at least a portion of its contractual obligations to OPM to provide medical services to its employees. The ARB reached this conclusion even though the hospitals' contracts with the UPMC Health Plan explicitly stated they were not federal contractors or subcontractors.

Similarly, in *OFCCP v. Florida Hospital of Orlando*, 2009-OFC-00002 (October 18, 2010),[3] a Department of Labor Administrative Law Judge (ALJ) held the hospital was a covered subcontractor, in part, because it had contracted with Humana Military Healthcare Services (Humana) to be a network provider for TRICARE beneficiaries. Humana had contracted with the U.S. Department of Defense to provide medical services to TRICARE beneficiaries. As such, the ALJ found the hospital had an agreement with Humana to assume some of its responsibility to provide health care services to TRICARE beneficiaries. Thus, it deemed the hospital a subcontractor and subject to OFCCP jurisdiction.

These cases demonstrate the OFCCP will assert jurisdiction over a hospital or health care provider as a federal contractor if it agrees to perform medical services or to provide products to federal health care programs even if it did not enter into an arrangement or contract directly with the federal government and even where it attempts to avoid OFCCP jurisdiction through explicit contract language.

However, not all contracts with a federal health care program will trigger the OFCCP's jurisdiction. In fact, there are a number of circumstances in which a hospital or health care entity will not be deemed a federal contractor or subcontractor even though it is involved with a federal health care program, including but not limited to where:

- It does not have a contract or subcontracts with the federal government in an aggregate value greater than $10,000 per year or a single contract worth at least $100,000 per year (or at least $25,000 per year if the contract was entered into before December 1, 2003);[4]
- It is merely receiving reimbursements from Medicare Parts A and/or B (or Medicaid) as Medicare is considered financial assistance which does not form a contractual relationship;[5]
- It is the recipient of a grant from a federal health care program as grants do not create a contractual relationship; and/or
- The underlying contract between the federal government and prime contractor only involves insurance reimbursements as opposed to the provision of medical services or products. See *OFCCP v. Bridgeport Hospital*, ARB Case No. 00-234 (January 31, 2003).

The foregoing is not an exhaustive list of arguments that can be asserted to contest one's alleged contractor, subcontractor status and/or the OFCCP's jurisdiction. Accordingly, hospitals should carefully and expeditiously review their connections to any federal health care programs before and/or upon receiving the notice. If this review shows a "federal contractor" or "subcontractor" relationship exists, the hospital should immediately contact counsel and determine whether it has to develop a written affirmative action plan and/or comply with the numerous other discrimination-related notice, posting and recording requirements that are enforced by the OFCCP.

As a result of the OFCCP's aggressive enforcement initiative towards the health care industry, all hospitals and health care providers should immediately take proactive steps to ensure they are in compliance with any applicable affirmative action obligations before receiving the dreaded notice. Failing to do so could result in a hospital being caught "flat footed" and unnecessarily incurring monetary penalties and/or having to engage in costly and time consuming litigation with the OFCCP.

For more information about this topic, please contact Kenneth A. Rosenberg at 973.994.7510 or krosenberg@foxrothschild.com or Todd A. Palo at 973.994.7541 or tpalo@foxrothschild.com.

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[2] The hospitals appealed this ARB decision to the U.S. District Court for the District of Columbia, Case No. 1:09-cv-01210.
[3] The hospital has appealed this ALJ decision to the ARB, ARB Case No. 11-011.
[4] The OFCCP has jurisdiction over an employer under (1) Executive Order 11246 where there is a contract or subcontract with the federal government in an aggregate value greater than $10,000 per year, (2) Section 503 of the Rehabilitation Act where there is a single contract worth $10,000 or more and (3) under VEVRAA where there is a single contract of at least $100,000.
[5] Note, the OFCCP has indicated that contracts related to Medicare Advantage Part C or D could trigger jurisdiction.

About the Health Law Practice

Fox Rothschild's Health Law Group comprises more than 40 attorneys who counsel clients locally, regionally and nationally. Our multioffice, multidisciplinary approach allows us to offer practical, cost-effective solutions to issues faced by longstanding stakeholders, as well as a variety of industry newcomers.

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