Health Law Advisory

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OIG's Update to the Provider Self-Disclosure Protocol Offers Expanded Detail and Transparency

The updated Provider Self-Disclosure Protocol (SDP) issued April 17, 2013 by the OIG expanded and updated the original SDP issued on October 30, 1998 and the OIG's Open Letters to health care providers issued subsequent to the original SDP. Both the original and the updated SDP provide guidance on how to investigate potential fraud, quantify damages and report the conduct to resolve the provider's liability under the OIG's civil monetary penalty (CMP) authorities. In its background comments, the OIG noted that it had resolved over 800 disclosures under the SDP amounting to more than $280 million in settlements over the past 15 years.

One of the announced purposes of the update was to provide a means for the OIG to communicate greater detail about how to investigate, report and calculate damages in some of the most common types of disclosures—false billing, conduct involving individuals excluded from federal health care programs and conduct or arrangements involving both the anti-kickback statute and Stark Law.

The updated SDP emphasizes the benefits of disclosure, including the belief that providers who self-disclose under the SDP and who cooperate with the OIG throughout the SDP process deserve to pay a lower multiplier on single damages than would be typically be required in a settlement of a government investigation. Further, the OIG pointed out that using the SDP may mitigate exposure under section 1128J(D) of the Social Security Act (42 U.S.C. 1320a-7k(d), the rule that requires reporting and repayment of a Medicare or Medicaid overpayment by the later of 60 days from the date the overpayment was identified or the date any corresponding cost report is due. CMS proposes to suspend the repayment obligation from the time a submission to the SDP is acknowledged by the OIG until a settlement agreement is entered or, the provider withdraws or

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is removed from the SDP. Once CMS issues a final rule, the OIG plans, if necessary, to issue additional guidance on its website correlating the rule to the SDP.

The OIG commits to working with providers who access the SDP and to streamlining the process to reduce the average time from acceptance to resolution to less than 12 months. Under the streamlined process, providers will be required to submit the findings from their competed internal investigation along with a damages' calculation within 90 days a the initial submission. The original SDP required the submission within 90 days of acceptance into the SDP.

As updated, the SDP continues to be available to health care providers, suppliers or other individuals or entities who are subject to the OIG's CMP authority. The SDP is only to be used to report conduct for which the reporter has liability---not to report the potential misconduct of other parties to report misconduct by others. The OIG Hotline 1-800 OIG-TIPS should be used for that purpose.

The SDP may not be used to obtain an opinion regarding whether or not a potential violation has occurred—the Advisory Opinion process should be used. The SDP is not available to report potential liability under Stark Law--the Self-Referral Disclosure Protocol is to be used to report Stark-only issues. Finally, mere overpayments without suspicion of fraud or legal violation should be handled through Medicare contractors and state Medicaid agencies.

Additional Detail in the Updated SDP:

- Disclosing parties will be expected, as a condition of admission to the SDP, to enter a tolling agreement with the OIG that waives the party's right to plead the statute of limitation, laches or similar defenses to any administrative action filed by the OIG related to the disclosed conduct except to the extents that such defenses would have been available to the disclosing party had an administrative action been filed on the date of submission.

- Disclosing parties are also expected to have terminated the improper arrangement or conduct within 90 days of submission to the SDP.

Although the original SDP had included an explanation of the necessary elements of the narrative of all submissions under the SDP, the updated SDP now adds specific requirements for disclosures pertaining to false billing, conduct involving persons excluded from federal health care programs (including instructions for calculating damages when the excluded individual did not bill separately for items or services, but whose costs were included in in cost reports) and conduct or arrangements involving both the Anti-kickback Statute and Stark Law.

The final section of the updated SDP sets out the details of resolution of submissions to the SDP: responsiveness and cooperation by the disclosing party, OIG coordination with the Department of Justice on civil matters and criminal matters and coordination with CMS with respect to conduct involving both the anti-kickback statute and Stark Law, minimum settlement amounts ($50,000 for Anti-kickback-related disclosures and $10,000 minimum for all other disclosures as well as procedures for disclosing parties unable to pay due to financial hardship.

The OIG also explains how overpayments refunded prior to entering the SDP may be credited toward the settlement amount subject to the OIG's review and acceptance of the methods for calculating the overpayment and subject to the multiplier. Finally, the OIG explains that submissions are subject to the Freedom of Information Act (FOIA) and trade secrets or other proprietary information included in the submission must meet the FOIA requirements for exemption in order to disclosing parties to be notified of disclosures pursuant to FOIA requests and other rights under the Act.

The updated SDP provides helpful instruction and insights that should assist parties disclosing in the future to better understand the process and to provide the necessary information and proper calculation of damages for frequently disclosed situations. ■

Julie A. Knutson

A Continued Challenge: The 3-Day Payment Rule Timeline

The Centers for Medicare and Medicaid Services' 3-day and 1-day payment rules (the "Payment Rules") continue to generate many questions among health care providers and suppliers concerning effective dates, changes, and application of the Payment Rules. Under the Payment Rules, a hospital (or an entity that is wholly owned or wholly operated by the hospital) must include on the claim for a beneficiary's inpatient stay the diagnoses, procedures, and charges for all outpatient diagnostic services and "admission-related" outpatient non-diagnostic services that are furnished to the beneficiary during the 3-day or 1-day window prior to the beneficiary's inpatient stay.[1] To better understand the application of the Payment Rules and changes in the "admission-related" standards, it is instructive to examine a timeline of the various changes to the Payment Rules:

a. March 13, 1998 – Payment Rules Effective. In 1998, CMS implemented the Payment Rules. The 1998 final rules state that the Payment Rules apply to diagnostic and "related non-diagnostic" outpatient services furnished by a hospital or an entity wholly owned or wholly operated by a hospital. The comments to the 1998 final rules include a hospital-owned physician practice as an example of a wholly owned or wholly operated entity. Therefore, the Payment Rules have applied to hospitals and wholly owned or wholly operated entities, including physician practices, since 1998. The 1998 rule defined "related" non-diagnostic services as those where there was an exact match between the ICD-9-CM diagnosis code for both the preadmission services and the inpatient stay.

b. April 4, 2011 – "Related to" Standard for *Hospital* Outpatient Services. As part of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010 ("PACMBPRA"), CMS implemented changes to the "related" standard as it applies to Hospital outpatient services. Therefore, if a hospital is examining past services subject to the Payment Rules (for example, to calculate a potential overpayment), it is important to pay attention to the dates of service and apply the correct "related to" standard. As of April 4, 2011, there is no longer a requirement for an exact ICD-9-CM diagnosis code match for hospital non-diagnostic outpatient services. Instead, for services after April 4, 2011, the services are deemed "related" to the inpatient admission, unless the Hospital attests that the non-diagnostic services are unrelated to the inpatient admission by using condition code 51 to the separately billed outpatient non-diagnostic services claim.

c. July 1, 2012 – "Related to" Standard for Wholly Owned/Operated *Physician Practice* Services. Following PACMBPRA and questions from providers and suppliers about the applicability of the new "related" rules, CMS published regulations specific to wholly owned or wholly operated physician practices regarding the "related to" standard. Beginning July 1, 2012, an exact ICD-9-CM diagnosis code match is no longer required. Instead, when submitting claims subject to the Payment Rules, a hospital must attest that the outpatient preadmission services provided in the wholly owned or wholly operated physician practice are clinically unrelated. In addition, the physician practice must identify "related" outpatient preadmission services by using the PD modifier.

It is important to remember that even though the specific "related" standards have changed, hospitals and physician practices have been subject to the Payment Rules since 1998. Therefore, any examination of past outpatient preadmission services subject to the Payment Rules could include an analysis under different "related to" standards, depending on the dates. Hospitals and wholly owned and wholly operated entities, including physician practices, should continue to implement proper policies and procedures to coordinate their billing to properly bill for diagnostic and related non-diagnostic services subject to the Payment Rules. ■

Michael W. Chase

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1. For a detailed discussion of the changes to the "related-to" standards, see the July 31, 2012 Baird Holm Health Law Advisory, available at http://www.bairdholm.com/media/newsletter/426 _ Health0712.pdf.

Federal Court Upholds OFCCP Jurisdiction Over Hospital

For years, we have been tracking the Department of Labor's Office of Federal Contract Compliance Programs' ("OFCCP") efforts to expand its jurisdiction to health care employers. Generally, the OFCCP enforces regulations that require employers with at least 50 employees, who hold a single contract or subcontract of at least $50,000 to provide services to the federal government, to comply with certain affirmative action obligations, including maintaining an affirmative action program ("AAP").

Health Care Institutions As Federal Contractors/ Subcontractors

Many health care organizations have a direct contract with the federal government, and therefore have affirmative action obligations by nature of that contract. For instance, a hospital may be a covered contractor as a result of a contract with the Department of Veterans' Affairs or the Department of Defense, requiring the provision of medical services to active or retired military personnel.

At the same time, a health care provider may have affirmative action obligations by nature of being a *subcontractor* to someone with a federal contract. In relevant part, a "subcontract" is any agreement between a contractor and any person for the purchase, sale, or use of non-personal services (1) that in whole or in part, are necessary to the performance of any contract, and/ or (2) under which any portion of the contractor's obligation under any contract is performed, undertaken, or assumed. Whether a health care provider's subcontracts bring it under the OFCCP's jurisdiction is a difficult inquiry, as it depends upon the nature of the underlying prime contract and the terms of the subcontract.

Brief Review of Prior Cases

In 1993, the OFCCP issued a directive concluding that Medicare or Medicaid reimbursement would not, absent other contracts, subject hospitals to its jurisdiction. The OFCCP concluded that Medicare and Medicaid were not contracts, but instead programs of federal financial assistance; therefore, the OFCCP had no jurisdiction over hospitals solely on the basis of Medicare/Medicaid reimbursement.

In a 2003 case entitled *OFCCP v. Bridgeport Hospital*, the DOL's Administrative Review Board ("Board") held that a hospital's contract with Blue Cross did not make it a subcontractor for affirmative action purposes. The Board held that because (1) the prime contract between Blue Cross and the agency was for medical insurance, and (2) the hospital was not in the business of providing insurance, the hospital was not a subcontractor because it did not perform work necessary to the performance of the prime contract to insure federal employees. Based on this decision, the consensus was that the OFCCP generally could not claim subcontractor coverage for hospitals, pharmacies or other medical care providers based solely upon the existence of a contract with Blue Cross or other Federal Employee Health Benefits Program ("FEHBP") providers.

The OFCCP, however, did not give up its attempts to assert jurisdiction over health care providers, and began focusing on health care providers that have contracts with health maintenance organizations (HMOs). In *OFCCP v. UPMC Braddock*, the Board held that a hospital was a subcontractor by nature of its contracts with an HMO. In that case, the Board made a distinction between an HMO and an insurance arrangement like the one at issue in *Bridgeport*, holding that, because the prime contract between the HMO and federal agency was to provide medical services to the federal employees, and the hospital provided *medical services*, the hospital was performing work necessary to the performance of the HMO's federal contract, which made them a subcontractor with affirmative action obligations.

The Board further held that the HMO's failure to notify the hospitals of any affirmative action obligations did not excuse the subcontractors' noncompliance. In other words, even if an organization does not know it is contracting with a federal contractor due to the absence of an Equal Employment Opportunity Clause in the contract, the organization may nevertheless be bound by the affirmative action regulations. This matter was appealed to federal court.

Recent Developments

On March 30, 2013, a federal court upheld the OFCCP's jurisdiction over the hospital in *Braddock.* The Hospital unsuccessfully attempted several arguments, including that it did not meet the definition of "subcontractor" because the medical services it performed did not qualify as

"nonpersonal services," and that the contract with the HMO was not a "subcontract" because the hospital did not provide services necessary to the HMO's performance of its contract with the government. The court rejected these arguments and held, "because the hospitals provide a portion of the medical care that the [HMO] agreed to supply to federal employees under its OPM contract, the hospitals' agreements with the [HMO] are necessary to the performance of that contract."

Even health care providers who only have TRICARE network arrangements should take this opportunity to review their contract status to assure nothing has changed in the last 18 months.

Finally, the hospital argued that it never consented to be bound by the EEO clauses in the laws and the Executive Order due to their absence from the contract with the prime contractor. The court disagreed, and held that "certain statutory or regulatory provisions may become part of a government contract even though the contract does not contain language to that effect." It essentially stated that because the hospital indirectly benefited from doing business with the federal government, it was subject to the EEO clauses. In the end, the court determined that the hospital was a subcontractor and was subject to affirmative action requirements.

Practical Effect of the Decision

In the end, this decision does not change what health care institutions already knew—that the OFCCP will continue its efforts to expand its jurisdiction over health care institutions. This case merely confirms the earlier findings of the Board, and solidifies the OFCCP's aggressive position on jurisdiction. This case does not change the TRICARE exclusion established in the December 2011 National Defense Authorization Act which held that TRICARE contracts alone are not enough to establish OFCCP jurisdiction. In other words, if the only federal contract/subcontract in place is a TRICARE contract, the health care institution does not have affirmative action obligations.

In light of the OFCCP's current aggressive stance, we advise health care providers to review their contracts and subcontracts and review their arrangements to assure that they do not fall under OFCCP jurisdiction. Even health care providers who only have TRICARE network arrangements should take this opportunity to review their contract status to assure nothing has changed in the last 18 months.

Employers uncertain about their contract status should seek legal counsel, or at the very least, should attempt to comply with affirmative action obligations voluntarily. In this way, if (or more likely, when) the OFCCP asserts jurisdiction on a different basis, health care employers will be better prepared to prove compliance. ■

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New MSA Status For Nebraska Counties May Impact Stark Physician Relationships

The U.S. Office of Management and Budget recently announced new Metropolitan Statistical Areas ("MSAs") based upon 2010 census data. In that announcement, a new MSA was created that includes Grand Island and the counties of Hall, Hamilton, Merrick and Howard. MSAs, by definition, have at least one urbanized area of 50,000 or more in population plus adjacent territory that has a high level of socio-economic integration. The new designation not only recognizes the growth of Grand Island and surrounding communities, but will have considerable impact on certain financial arrangements between hospitals (regardless of location) and physician-owned entities in the areas included in the new MSA.

There are no Stark compensation exceptions based upon rural location. However, the "rural provider" exception permits physician ownership in (and thus physician referrals to) rural non-hospital entities. In order to qualify for the rural provider exception, substantially all of the designated health services furnished by the entity must be furnished to individuals who reside in a "rural area." The regulations define "substantially all" as being not less than 75% of the designated health services the entity furnishes.

The key to qualifying for the "rural provider" exception is the definition of "rural area." Under Stark, a "rural area" is any area that is not in an MSA. For purposes of the rural provider exception, designated health services provided to patients residing within an MSA are not considered to be services provided to residents of rural areas. Thus, these services will not count toward satisfying the 75% threshold.

Just because a physician-owned entity is located within the new MSA does not per se mean that the entity no longer qualifies as a rural provider.

It is important to recognize that qualification for the rural provider exception is not based upon the location of the physician-owned entity, but the location where the entity provides substantially all of its services. That is, just because a physician-owned entity is located within the new MSA does not *per se* mean that the entity no longer qualifies as a rural provider. Nonetheless, it is highly likely that physician-owned entities based in an MSA will fall into the rural provider definition unless they provide most of their services outside of the community. Thus, a physician-owned entity located in the new Grand Island MSA that previously relied upon the "rural provider" exception to protect referrals of designated health services by its physician owners may no longer be available and may have to be restructured.

The new Grand Island MSA also has the potential to significantly impact hospitals[1] that do business with physician-owned entities that are based in the new MSA. In 2009, CMS revised the Stark regulations in a manner that prohibited most "under arrangement" relationships with physicians.[2] Subsequent to that change, the only realistic way a hospital could continue to enter into an "under arrangement" financial relationship with a physician-owned entity was if that physician-owned entity qualified as a rural provider under the rural provider exception. It was through the rural provider exception that physicians could continue to make referrals to their own entity providing the under arrangement service. If the entity failed to qualify as a rural provider, the arrangement would result in a Stark violation to the extent a physician-owner continued to refer patients to his or her entity.

In the preamble to the Phase III Stark rules, CMS indicates that it will not grandfather arrangements based upon prior MSA status. That is, if an entity qualified for rural provider status when it was created and an MSA designation changed, the entity would not continue to qualify as a rural provider. In CMS's opinion, "a physician who invests in an entity furnishing DHS in a rural area takes a risk that the area will subsequently be classified as an urban area." Thus, if a physician-owned entity no longer qualifies for rural provider status based upon a new MSA designation, any under arrangement contracts with that physician-owned entity must be unwound to the extent the physician owners will continue to make referrals to the entity.

As a result of the new Grand Island MSA, we suggest that hospitals review their relationships with physician-owned entities located in the applicable counties to determine whether or not any of those relationships constitute "under arrangement" agreements. If any such arrangement exists, it will need to be determined whether the physician-owned entity continues to qualify as a rural provider based upon the locations in which it provides substantially all of its services. If, after review, it is determined that the entity no longer satisfies the rural provider exception, the arrangement will need to be promptly unwound. ■

Andrew D. Kloeckner

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1. This includes hospitals that are outside of the new MSA.

2. Under arrangement relationships are relationships where an entity essentially provides the entire service to the hospital, including the technical staff and equipment.

Upcoming Speaking Engagements

Julie A. Knutson and Michael W. Chase will present at the Nebraska MGMA Spring Meeting, "It Can Happen in Your Office: How to Prepare for and Respond to Investigations and Audits," May 10, 2013.

Vickie B. Ahlers will present at several meetings and conferences this spring:

- IMGMA Spring Conference, "HITECH Final Regulations and Enforcement," May 9, 2013
- ISHA Spring Conference, "The Next Decade of HIPAA: Understanding and Implementing the Omnibus Final Rule," May 14, 2013
- Nebraska HIMSS Spring Meeting, "HIPAA Privacy Update," May 21, 2013
- Nebraska Hospital Association Mid-Year Meeting, "Scary Situations: Protecting Your Hospital from Violent Patients, Employees or Visitors," May 23, 2013 (co-presenting with Heidi Guttau-Fox) ■

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