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### JOINT COMMISSION REVISES HOSPITAL REQUIREMENTS TO ALIGN WITH CMS CONDITIONS OF PARTICIPATION

The Joint Commission (JC) recently published new and revised elements of performance (EPs) for several of its accreditation standards for hospitals and critical access hospitals (CAHs), which took effect on July 2, 2014. The JC revised the EPs in connection with its application to the Centers for Medicare and Medicaid Services (CMS) for renewal of the JC's deeming authority. The purpose of the revisions is to demonstrate equivalency between the EPs and CMS' Medicare Conditions of Participation. The following JC standards contain new or revised EPs: Environment of Care; Human Resources; Leadership; Medication Management; Medical Staff; Nursing; Provision of Care, Treatment, and Services; Record of Care, Treatment and Services; and Rights and Responsibilities of the Individual. The new EPs are available in their entirety here.

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### OIG RELEASES SPECIAL FRAUD ALERT REGARDING LABORATORY PAYMENTS TO REFERRING PHYSICIANS

The Office of the Inspector General (OIG) recently issued a Special Fraud Alert (the Alert) regarding compensation paid by laboratories to referring physicians and physician group practices for blood specimen collection, processing, and packaging (Specimen Processing Arrangements) and for submitting patient data to a registry (Registry Arrangements).

The OIG views Specimen Processing Arrangements and Registry Arrangements as "inherently suspect" under the Anti-Kickback Statute (AKS). In the Alert, the OIG highlights a number of characteristics of each type of arrangement that will trigger heightened scrutiny of Specimen Processing and Registry Arrangements.

**Potential for Violation of the Anti-Kickback Statute**

Any arrangement between a laboratory and a physician or physician group practice that creates an opportunity for a referring physician to profit from referrals for health care services paid for by a federal health care program implicates the AKS.

In the Alert, the OIG explains that laboratory payments to physicians in Specimen Processing and Registry Arrangements present opportunities for laboratories to provide physicians with payments that are not commercially reasonable in the absence of Federal health care program referrals. Such payments

may induce physicians to order tests from a laboratory that provides them with remuneration and to order medically unnecessary or duplicative tests, rather than the most clinically appropriate service from a superior laboratory. Any payment for the purpose of inducing referrals is unlawful under the AKS and a payment to an individual or entity in a position to generate referrals that exceed fair market value or will also be paid by a third party is subject to increased scrutiny and may violate the AKS. The OIG notes that the potential for fraudulent conduct is heightened in the context of laboratory payments to physicians that are tied to the volume or value of business the physician generates, because the decision to order laboratory tests and the choice of laboratory are typically made by the physician, with little or no input from patients.

**Suspect Characteristics of Specimen Processing Arrangements**

The OIG lists a number of "suspect characteristics" of Specimen Processing Arrangements that may be evidence of unlawful purpose, including, but not limited to:

- A payment that is also made by a third party, including Medicare; is in excess of fair market value for services actually rendered; or is tied to the volume or value of referrals.
- The ordering physician receives payment for specimen processing directly, rather than the payment going to the ordering physician's group practice, which may bear the actual costs of collecting and processing specimens.
- A payment is offered on the condition that the physician order either (1) a specified type of test or test panel, especially if the panel includes tests that use different methodologies intended to provide the same clinical information or (2) are otherwise unnecessary or non-reimbursable.
- The physician or the physician's group practice receives payment for specimen processing, although the specimen processing is being performed by a phlebotomist placed in the physician's office by the laboratory or other third party.

**Suspect Characteristics of Registry Arrangements**

Registry Arrangements are those under which laboratories coordinate or maintain databases, directly or through an agent, to collect data on the demographics, presentation, diagnosis, treatment, outcomes, or other attributes of patients who have undergone, or may undergo, certain tests, generally specialized and expensive tests paid for by Federal health care programs, performed by the offering laboratories. The OIG also lists a number of "suspect characteristics" of Registry Arrangements that may be evidence of unlawful purpose, including, but not limited to:

- Requirements or recommendations that physicians perform tests with a certain frequency to receive, or avoid a reduction in, compensation.
- Collection of comparative data from, and billing for, tests that are duplicative or otherwise unnecessary.
- Collection from only a subset of physicians who were selected on the basis of their prior or anticipated referral volume, rather than their specialty, sub-specialty, or other relevant attribute.
- Compensation that is paid to physicians (1) takes into account the value or volume of referrals; (2) is not fair market value of services rendered in collecting and reporting patient data; or (3) is not supported by documentation, submitted by the physician in a timely manner, memorializing the physician's efforts.
- The laboratory offers Registry Arrangements only for tests or disease states associated with tests for which it has obtained patents or that it exclusively performs.

**Other Highlights of the Special Fraud Alert**

The OIG advises that in determining the fair market value of a physician's services, the proper considerations for a laboratory include whether the services for which payment is being made have been, or may be, paid for by Medicare, including through a bundled payment. The OIG also directs laboratories to consider whether the services are paid for by a third party through other means, such as payments intended to reimburse the physician for overhead expenses.

In addition, the OIG cautions that Specimen Processing and Registry Arrangements that "carve out" Federal health care program business from otherwise questionable arrangements do not abate the OIG's concerns regarding fraudulent conduct under the AKS. The agency further warns that an otherwise unlawful Registry Arrangement will not be protected by claims that registries are intended to promote and

support clinical research and treatment, or by retaining an independent Institutional Review Board to develop study protocols and participation guidelines.

In light of the Alert, laboratories, physician groups, and physicians may want to review any existing or potential Specimen Processing and Registry Arrangements to ensure that the arrangements do not involve characteristics that could be subject to scrutiny by the OIG.

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Please contact any member of the Health Law Group at Robinson+Cole if you have questions:

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