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Health Headlines

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Institute Of Medicine Recommends Changes To The Way Medicare's Geographic Adjustment Is Calculated – In a report released last week, the Institute of Medicine (IOM) recommended that changes be made to increase the accuracy of Medicare's geographic adjustment. Medicare is a nationwide program, but the payments made to health service providers vary across regions in order to account for differences in overhead costs, which are typically higher in metropolitan areas. Geographic adjustments for hospitals are determined by the hospital wage index (HWI), whereas adjustments for physicians' offices are determined by the geographic practice cost index (GPCI). The IOM believes that geographic adjustment should be modified to make it more accurate. The adoption of these recommendations would increase Medicare payments in some areas, while decreasing the amount of payments in others.

Currently, the geographic divisions used to adjust payments differ for payments made to a hospital versus payments made to a physician. The Institute of Medicine found this distinction to be unwarranted, and it recommended that one set of geographic divisions be used for both hospitals and physicians. The report also recommends that the index used to adjust payments to hospitals and the index used to adjust payments to physicians use health sector data from the Bureau of Labor Statistics. For both hospitals and physician offices, the report recommends that a wider range of occupations in the healthcare industry be included in their respective indexes. The different occupations would be weighted for the hours worked by that occupation and the occupation-specific weight would be consistent nationwide. As a result, the Institute of Medicine believes that the index will reflect the price, rather than the reported cost of labor.

There presently may be large differences in the adjustment under either the HWI or the GPCI on either side of a border between two geographic adjustment areas. The report makes an effort to smooth out the borders by taking commuting patterns of employees into account. The "smoothing of borders" is intended to replace the current system of geographic reclassifications and exceptions.

The IOM's recommendations are intended to increase accuracy and to be budget neutral. If the recommended changes do affect the total amount of payments made to healthcare providers, the report instructs the Centers for Medicare and Medicaid Services to re-calibrate the payments to maintain budget neutrality. For a copy of the report, click **here**.

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GME Affiliation Agreements Due On July 1 – The deadline for teaching hospitals to submit graduate medical education (GME) affiliation agreements for the upcoming academic year to the Centers for Medicare and Medicaid Services (CMS) is 11:59 p.m. on July 1, 2011. Historically, CMS has taken a very hard line that hospitals abide by the deadline. In email notifications and during the June 1, 2011 Hospital Open Door Forum, CMS has encouraged hospitals to submit affiliation agreements in PDF form by email to Medicare_GME_Affiliation_Agreement@cms.hhs.gov. However, CMS will accept paper copies of affiliation agreements one final time for this coming academic year. CMS representatives have said that

hospitals that electronically submit their affiliation agreements will receive an automatic reply indicating the agreement was timely received. All hospitals that are party to an affiliation agreement must submit copies of the agreement, and each must copy its individual Medicare contractor using the contractor's preferred submission method. Contractors are not required by CMS to accept electronic submissions. Hospitals with existing affiliation agreements that automatically renew on July 1 may, but are not required to, submit those agreements to the CMS email address.

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CMS FAQs On Advanced Diagnostic Imaging Accreditation – On May 24, 2011, the Centers for Medicare and Medicaid Services (CMS) posted 10 new FAQs related to Advanced Diagnostic Imaging Accreditation. Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required the Secretary to designate organizations to accredit suppliers that furnish the technical component (TC) of advanced diagnostic imaging services. Such services include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine imaging such as positron emission tomography. Pursuant to 42 C.F.R. § 414.68, by January 1, 2012, suppliers, including but not limited to physicians, non-physician practitioners and Independent Diagnostic Testing facilities that furnish the TC of advanced diagnostic imaging services for Medicare beneficiaries are required to be accredited.

The recent CMS FAQs related to the Advanced Diagnostic Imaging Accreditation includes discussion of the following:

- The accreditation rule does not apply to hospitals.
- Although the accreditation requirement only applies to the suppliers producing the images themselves, all interpreting physicians must meet the accreditation organizations' published standards for qualifications and responsibilities of medical directors and supervising physicians (i.e., requirements related to residency program training and continuing medical education).
- If entities would like to supply the TC after the January 1, 2012 accreditation deadline, they must be accredited at the time that they apply for Medicare enrollment.
- The designated accreditation organization will transmit its findings to CMS or its contractor when its decision becomes final.
- MIPPA excludes from the accreditation requirement x-ray, ultrasound, and fluoroscopy procedures, as well as diagnostic and screening mammography which are subject to quality oversight by the FDA.
- If a supplier is accredited before January 1, 2010 by one of the designated accreditation organizations, it must apply for re-accreditation within the timeframe specified by the accreditation organization instead of meeting the January 1, 2012 deadline.
- After submission of a completed application, and depending on the complexity of the organization (i.e., number of locations), the average time to become accredited is generally four to five months.
- The three national accreditation organizations approved by CMS include the American College of Radiology, the Intersocietal Accreditation Commission and The Joint Commission.

The FAQs are available **here** by searching for "Advanced Diagnostic Imaging Accreditation" and the CMS website for Advanced Diagnostic Imaging Accreditation is available **here**.

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HRSA Proposes Regulations Interpreting 340B Program Orphan Drug Exclusion For Newly Covered Entities – On May 20, 2011, the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS) published a proposed rule to implement the statutory provision excluding orphan drugs from the 340B drug discount program for certain entities that became eligible for the program as a result of healthcare reform. 76 Fed. Reg. 29183 (May 20, 2011).

Under the 340B program, manufacturers are required to provide outpatient drugs at a discount to certain providers, called "covered entities." The orphan drug exclusion applies only to entities that participate in the program as free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Proposed 42 C.F.R. § 10.21(b). Under HRSA's proposed regulations, "a covered outpatient drug does not include orphan drugs that are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated

under [the Federal Food, Drug, and Cosmetic Act (FFDCA)]." Proposed 42 C.F.R. § 10.21(a). However, for these same covered entities, a covered outpatient drug includes designated orphan drugs that are transferred, prescribed, sold, or otherwise used for any indication other than that treating the rare disease or condition for which the drug was designated under section 526 of the FFDCA. 76 Fed. Reg. at 29186.In other words, the entities to which the orphan drug exclusion applies can purchase these drugs at 340B prices when using them for common conditions for which they are approved or any other lawful use except when using them for the rare condition or disease for which they were given an orphan drug designation. *Id.*

The proposed regulations also require covered entities "to ensure that orphan drugs that are purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which orphan drugs are designated under [the FFDCA]." Proposed 42 C.F.R. § 10.21(c). Covered entities must maintain auditable records to demonstrate their compliance. *Id.* The proposed rule does not state what sanctions will apply in the case of nonperformance.

The orphan drug exclusion does not apply to children's hospitals. Children's hospitals became eligible to participate in the 340B Program under the Deficit Reduction Act of 2005, but were not part of the definition of "covered entities" until the passage of the Patient Protection and Affordable Care Act (PPACA) as part of healthcare reform. At that time there was controversy surrounding the application of the drug exclusion to children's hospitals. On December 15, 2010, the Medicare and Medicaid Extenders Act amended the orphan drug exclusion's statutory language to clearly indicate that the orphan drug exclusion did not apply to children's hospitals.

HRSA cited three rationales for its proposed rule. First, HRSA recognized confusion regarding to which covered entities and to which uses of orphan drugs the exclusion applied, as well as record-keeping and compliance requirements. The new regulations provide clearer guidance. Second, HRSA wanted to maintain the savings provided by the 340B program. Since many of the entities to which the exclusion applies are significant orphan drug purchasers, HRSA interpreted the Affordable Care Act to prohibit the purchase of orphan drugs through the 340B program only for uses for which the drug was designated under the FFDCA, thus continuing to provide covered entities with significant savings. Third, HRSA wanted to protect manufacturers' financial incentives to produce orphan drugs for rare conditions and diseases. The exclusion is consistent with those incentives.

The Secretary of HHS signs agreements with pharmaceutical companies creating binding maximum prices for drugs sold to covered entities. More than 15,000 entities currently purchase more than $3.4 billion in drugs at a 30 to 50 percent discount under the program. HRSA estimated that the proposed rule would save an additional $20 to $30 million in drug acquisition costs.

Comments on the proposed rule are due July 19, 2011. The full text of the proposed rule is available **here**.

Reporter, Charles E. Smith, Washington, D.C., +1 202 626 5524, csmith@kslaw.com.

FDA Issues Draft Guidance For Clinical Investigators, Industry And FDA Staff: Financial Disclosure By Clinical Investigators – The Food and Drug Administration (FDA) issued draft guidance on May 24th describing its current thinking on the disclosure of financial interests of clinical investigators updating the prior decade-old guidance issued on the subject. The new draft guidance is notable in that it provides more information regarding the sponsor's responsibility to collect the required disclosure information, provides more information about the due diligence expected of an applicant in collecting the information required in a marketing application, and provides detail regarding how FDA will review and perhaps disclose the financial information it receives. Electronic or written comments on the draft guidance should be submitted by July 25, 2011.

Sponsor's Collection of Required Disclosure Information

The draft guidance notes that the sponsor of a covered study is in a unique position to both obtain the financial information that may be needed if or when the study is submitted years later. Furthermore, the financial information collected may serve to alert the sponsor of potential conflicts of interest and thus allow it to minimize any potential for

study bias. Under the regulations, any clinical investigator who is not a full-time or part-time employee of the study sponsor must provide the sponsor with sufficient and accurate financial information to allow for complete disclosure or certification and to update the financial information if any relevant changes occur either during the study or for one year after its completion.

FDA notes that it is Agency policy to review financial disclosure information provided to a sponsor by a clinical investigator during a bioresearch monitoring (BIMO) inspection, and that it is entitled to access and copy supporting documentation.

Due Diligence Expected under 21 C.F.R. Part 54

Under 21 C.F.R. Section 54.4, an applicant must exercise "due diligence to obtain the information required in this section" and if unable to obtain the information "the applicant shall certify that despite the applicant's due diligence in attempting to obtain the information, the applicant was unable to obtain the information and shall include the reason." FDA's prior March 20, 2001 guidance simply referred to due diligence and provided a brief discussion. In contrast, the new draft guidance provides specific detail regarding FDA's recommendations for the certification of due diligence: "FDA recommends that sponsors and/or applicants try to locate the clinical investigator through at least two telephone calls and make written memoranda of their calls and any telephone conversations." Applicants should also follow up these calls in writing and send at least two certified letters to locate missing investigators. FDA expects the applicant to request contact information for the investigator if he/she is no longer at the institution where the study was conducted, to contact professional associations, and to conduct internet searches to locate the investigator. An applicant must exercise due diligence whether a covered study was conducted domestically or internationally.

FDA Review of Financial Information and Potential Disclosure

draft guidance sheds additional light on how the financial disclosure information will be reviewed and used by FDA. When evaluating the information disclosed, FDA will assess the level of concern raised by the amount and nature of the specific financial interest. For example, it noted that payments that may be affected by the outcome of the study elicit the highest level of concern. The most common financial interests disclosed by investigators are equity interests and significant payments of other sorts (SPOOS). In determining whether action is indicated due to the financial interests, FDA may consider factors such as the number of investigators used, the total number of subjects and investigators, the number and percentage of subjects enrolled by the disclosing investigator, and whether the investigators are blinded to the randomization allocation. FDA reviewers may also compare the study results from more than one investigator and re-analyze the data, excluding the results from the disclosing investigator to determine if results can be replicated. Importantly, FDA stated its reviewers will consider the description of steps taken by the sponsor to minimize the potential bias of study results from disclosed financial interests submitted on Form FDA 3455.

Another notable distinction in the draft guidance from FDA's prior guidance is with regard to public disclosure of financial interests. The prior guidance indicated that clinical investigators' equity interests "would be protected from public disclosure unless circumstances relating to the public interest clearly outweigh the clinical investigator's identified privacy interest" and stated that "only rarely" would an investigator's privacy interest be outweighed by public interest. The draft guidance reflects a change not only at FDA but also in industry generally. It states that multiple entities "including federal and state governments, institutions, companies, and other organizations, are developing and implementing policies on public disclosure of industry financial arrangements." FDA acknowledged the growing interests in clinical investigator equity interests and noted that much of this information is already in the public domain. Stating that it is currently developing its transparency policy, FDA noted that the policy may affect what information, and in what manner, it publicly discloses the financial interests and arrangements of clinical investigators. FDA is seeking comments on the various options for disclosure, including whether the information disclosed should be a summary of information, a listing of interests and arrangements without identification of the investigator, or a listing that identifies the investigator.

The full text of the draft guidance is available **here**.

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Ninth Circuit Overturns Dismissal Of Physician's Claim Alleging Retaliatory Discharge For Whistleblowing – In an unpublished opinion dated May 27, 2011, the United States Court of Appeals for the Ninth Circuit remanded to the federal trial court a California physician's (Dr. Van A. Pena) claim that his whistleblowing activities led defendants Sonoma Development Center (SDC), SDC Executive Director Timothy Meeker, and SDC Medical Director Judith Bjorndal to terminate his employment. According to the Ninth Circuit, Pena presented sufficient evidence to allow the question of the retaliatory discharge to go to the jury.

Pena claimed that he was fired in retaliation for a confidential complaint he submitted to the California Department of Health Services (DHS) regarding removal of patient photographs from files at SDC. As a result of Pena's DHS complaint, DHS issued a Statement of Deficiencies to SDC and required SDC Executive Director Timothy Meeker to implement a Plan of Correction modifying SDC policies for removal of patient photographs. According to the court, Pena presented evidence that, exactly one week after SDC implemented its Plan of Correction, Pena's habit of taking patient photographs was raised as a "big issue" at a meeting attended by Bjorndal and Meeker. Pena also presented evidence that he had a reputation among his superiors at SDC "as a repeat whistleblower whose complaints of patient mistreatment threatened to subject SDC to legal liability."

In granting summary judgment in defendants' favor, the district court concluded that Pena failed to raise a genuine issue of material fact as to whether Bjorndal knew he was the individual responsible for the DHS complaint. The Ninth Circuit disagreed. "That SDC supervisory personnel viewed Pena as a troublesome whistleblower and that his taking of patient photographs was raised at both an executive committee meeting and in a meeting between Bjorndal and Pena only one week after the SDC had been compelled by DHS to implement a Plan of Correction on the subject of patient photographs provides strong circumstantial evidence from which a reasonable factfinder could infer that SDC leadership, including Bjorndal, suspected Pena of having filed the DHS complaint and retaliated against him on that basis."

The Ninth Circuit also held that the district court, at Pena's first trial, improperly excluded testimony from Ed Contreras, SDC police chief, that Meeker ordered him to "find dirt" on Pena. "Because a retaliation suit 'requires a showing of an employer's improper motive. . . retaliation cases often turn upon circumstantial evidence. Here, the fact that SDC leaders, including Bjorndal's direct superior, desired Pena's termination so strongly that they were willing to engage the SDC Police Chief in a cloak-and-dagger investigation of Pena would allow a jury to infer that those leaders would have communicated that desire to Bjorndal." This evidence, the Ninth Circuit said, was highly probative and any possible prejudice could be addressed by the defendants' testimony.

Finally, Pena also appealed the district court's grant of summary judgment to defendants on Pena's claim that he was discharged in retaliation for exercising his First Amendment rights by complaining to Bjorndal of mistreatment of patients at SDC. The Ninth Circuit affirmed the district court's ruling, holding that Pena's reporting of mistreatment to an SDC superior "fell squarely within his official duties as an SDC physician, [and therefore] he was not entitled to First Amendment protection for that action . . ."

A copy of the Ninth Circuit's opinion is available **here**.

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