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Stark phase III provides clarification, eases regulatory burden, relaxes physician recruitment rules

by Matthew Mann, J.D., Contributing Editor

The CMS final rule prohibiting physician self-referrals, referred to as Stark Phase III, clarifies and revises existing regulations but does not add any new exceptions to the self-referral prohibitions. The Phase III final rule, which was released on September 5, 2007, responds to comments solicited on the Phase II interim final rule issued by CMS on March 26, 2004. (*See Health Care Compliance Reporter* ¶177,001).

New and revised definitions. The definition of "fair market value" has been revised in Phase III to eliminate the safe harbor regarding hourly payments for a physician's personal services. CMS emphasized, however, that it will continue to scrutinize the fair market value of arrangements, as it is an essential element of many exceptions. The appropriate method for determining fair market value, according to the final rule, will depend on "the nature of the transaction, its location, and other factors." The definition of "'incident to' services" has been modified to clarify that the term includes both services and supplies (such as drugs) that meet the applicable requirements set forth in §1861(s)(2)(A) of the Social Security Act, applicable CMS regulations, and relevant CMS manual provisions. The definition of "physician in the group practice" has been revised to clarify that a physician who is an independent contractor of a group practice must furnish patient care services for the group under a contractual arrangement directly with the group practice.

Definitions also have been added for "downstream contractor," "physician organization," and "rural area." A downstream contractor is defined by the final rule as both a "first tier contractor" (*see* 42 C.F.R. §1001.952(t)(2)(iii)) and a "downstream contractor" (*see* §1001.952(t)(2)(i)). Therefore, for physician self-referral purposes, a downstream contractor includes an individual or entity that has a contract directly with an eligible managed care organization (MCO) to provide or arrange for items and services (*i.e.*, a first tier contractor) and an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision of or arrangement for items or services that are covered by an agreement between an eligible MCO and the first tier contractor. A physician organization has been defined as a "physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of 42 C.F.R. §411.352." A rural area is defined simply as an area that is not an urban area as defined at 42 C.F.R. §412.62(f)(1)(ii).

Physician recruitment and retention. The Phase III final rule provides enhanced flexibility in structuring nonabusive compensation arrangements. CMS made several significant changes to the physician recruitment exception, including:

- permitting rural health clinics to use the exception;
- deeming the geographic area served by a hospital to be the area comprised of all the contiguous zip codes from which the hospital's inpatients are drawn when the hospital draws fewer than 75 percent of its inpatients from contiguous zip codes;
- permitting a rural area hospital to utilize an alternative test to determine the "geographic area served by the hospital;"
- permitting more generous income guarantees in limited circumstances;
- permitting group practices to impose certain practice restrictions;
- permitting recruitment outside a rural hospital's geographic service area if it is determined through a CMS advisory opinion that there is a demonstrated need; and
- exempting certain physicians from the relocation requirement.

In addition, CMS has expanded the retention payments in underserved areas exception to permit a hospital to make a retention payment to a physician on its medical staff even if the physician does not have a bona fide firm, written recruitment offer, provided that the physician certifies in writing that, among other things, he or she has a bona fide opportunity for future employment that would require the physician to move his or her medical practice at least 25 miles to a location outside the geographic area served by the hospital.

"Stand in the shoes" provision. A provision also has been added to provide that a physician will be deemed to have a direct compensation arrangement with an entity furnishing designated health services (DHS) if the only intervening entity is his or her physician organization. Under §411.361(c)(2), referring physicians will be treated as "standing in the shoes" of their group practices for purposes of applying the rules that describe direct and indirect compensation arrangements. As a result, many compensation arrangements that were analyzed under Phase II as indirect are now analyzed as direct compensation arrangements that must comply with an applicable exception.

Relief for inadvertent violations. Under the final rule, parties that inadvertently exceed the limit on nonmonetary compensation may continue to satisfy the requirements of the exception if the excess nonmonetary compensation does not exceed 50 percent of the permitted amount and is repaid within 180 days of its receipt or the end of the calendar year, whichever is earlier.

Miscellaneous revisions. The Phase III final rule provides that an ownership or investment interest does not include a physician's security interest in hospital equipment when the physician sold the equipment to the hospital and financed its purchase through a loan to the hospital. In addition, the final rule reduces the regulatory burden for compliance with certain exceptions by, for example, eliminating the requirement that entities providing professional courtesy provide written notice to an insurer of a reduction of any coinsurance obligation.

CMS also modified the intra-family rural referrals exception to include an alternative distance test based on transportation time from the beneficiary's residence. Phase II utilized a 25–mile test to determine whether the exception applied in a particular situation. Under the alternative test, a physician may refer a patient to an immediate family member for DHS if the DHS cannot be provided otherwise within 45 minutes transportation time from the patient's home at the time the DHS referral is made.

Finally, CMS has clarified the academic medical centers exception. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all physicians holding the same class of privileges at the affiliated hospital.■

Final rule, 72 FR 51012, Sept. 5, 2007, Health Care Compliance Reporter, ¶700,050.

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Designer
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Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

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MSP statute does not provide for *qui tam* action

by Jay Nawrocki, Contributing Editor

The Medicare Secondary Payer (MSP) statute does not authorize a private organization or individual to bring suit on behalf of the federal government, according to the United States Court of Appeals for the First Circuit and a federal district court in New York. Both courts recently dismissed MSP claims based on lack of constitutional standing.

In the First Circuit case, an advocacy group for seniors was unsuccessful in its attempt to force five tobacco companies to reimburse the Medicare program under the MSP statute for money the program had expended since 1999 to pay for treatment of smoking-related illnesses. In the New York district court case, an individual's claim that a Medicare intermediary and carrier failed to collect money owed to Medicare in accordance with the MSP statute likewise was dismissed.

Lack of standing. Under the MSP statute, a Medicare payment "may not be made ... with respect to any item or service to the extent that payment has been made or can reasonably be expected to be made" under a primary plan. Should Medicare determine that the primary insurer has not and cannot reasonably be expected to pay, Medicare may make a conditional payment to the beneficiary. The MSP statute provides for a government action as well as a private cause of action to enforce Medicare's right to reimbursement in the event that a primary plan later pays or is found responsible for payment of the item or service.

The advocacy group and the individual claimed standing to sue under the MSP as representatives of the federal government, which allegedly was charged incorrectly for treatment of Medicare beneficiaries. Both federal courts rejected the claims, however, concluding that the MSP statute is not a *qui tam* statute that allows private organizations and individuals to sue to redress injuries sustained by the government.

To bring a case to court, an organization or individual must establish three elements: (1) an injury in fact; (2) a causal connection between the injury and the alleged wrongful conduct; and (3) redressability of the alleged injury. The advocacy group in the First Circuit case failed to demonstrate an injury in fact because it did not assert that any of its members was a Medicare beneficiary. Similarly, the individual who brought suit in the New York district court was not a Medicare beneficiary and did not claim to have suffered actual harm as a result of the alleged wrongful conduct.

Additionally, both courts reasoned, there is no evidence of congressional intent to authorize a *qui tam* cause of action under the MSP statute. The MSP statute lacks typical characteristics of a *qui tam* statute, the courts explained. First, Congress added a private cause of action to the MSP statute in the same month and year it added a true *qui tam* provision to the federal False Claims Act (FCA). The MSP statute provides for a private organization or individual to sue a private plan for failure to pay a health care claim, but it does not provide for a private organization or individual to sue on behalf of the federal government, nor does it provide for private individuals or organizations to share a percentage of any recovery with the government. The absence of a *qui tam* exception to the constitutional standing requirements suggests that Congress unequivocally did not intend to authorize a *qui tam* cause of action under the MSP statute.

Second, the MSP statute, unlike the FCA, does not describe a scenario in which a private organization or individual is suing on behalf of the federal government, and the federal government is the true interested party. Third, the MSP statute has a provision for the government to initiate its own cause of action separate from any private cause of action.

Finally, the MSP statute lacks the procedural safeguards typically found in a *qui tam* statute that are designed to ensure that the government remains fully apprised of the litigation, has the opportunity to participate, and retains the power to make key decisions over the private organization or individual's objections.■

United Seniors Association Inc. v. Philip Morris USA, 1st Cir., Aug. 20, 2007; Woods v. Empire Health Choice Inc., E.D.N.Y., Aug. 20, 2007.

On The Front Lines

A structured approach to developing an effective internal audit program for billing and coding

by Michael Miscoe, CPC, CHCC, CRA, Contributing Editor

Internal audits are an essential part of a compliance program; however, to make an audit program effective, organizations must first understand the purpose of an audit as well as the steps necessary to conduct the audit appropriately.

Compliance is a word that is used often but truly understood by few. Most physicians approach compliance as a necessary evil, or possibly even as a goal that the organization must achieve. It is neither. Compliance is a process, not a result. The reason that an organization should implement compliance processes is to ensure that it is being paid appropriately. This includes avoiding the types of errors that will lead to either post-payment liability for inappropriate payments or claims errors that will lead to inappropriate denials or diminished reimbursement.

Collecting accurate reimbursement often eludes many, regardless of whether they internally audit or not. An effective audit program is necessary to ensure not only that the organization gets paid the correct amount, but also that it can justify its right to keep the money. For an audit to be effective, it must entail an objective comparison between the information relative to what was performed and the appropriate rules defining the health plan's obligation for payment. Because of the perceived difficulty in understanding the "rules" governing reimbursement, many organizations under-report services as a strategy to avoid post-payment liability. This approach is often very expensive (based on lost revenue) and does not provide the peace of mind as to whether the organization is "compliant" that an effective auditing program will provide.

There are two key processes involved in compliance: education and auditing. The purpose of auditing is to find and correct mistakes before claims are submitted for payment consideration by a third party health plan or government contractor. As the organization identifies mistakes, its members also learn useful information that helps them understand where additional training is required. As such, the two processes are interrelated; however, this article will only focus on the auditing process.

For those without formal audit training, HHS, the Office of Inspector General (OIG) and the Office of Audit Services (OAS) have developed a guide that explains the audit process in detail. It is recommended reading for all involved in the audit process and can be found on the Internet at http://oig.hhs.gov/organization/OAS/OIGAuditProcess.pdf. While this guide is structured toward the conduct of government audits, it is also useful to the in-office auditor as a tool for ensuring that an audit program is effective.

As detailed in the guide, a properly designed audit process occurs in four phases. These include the planning phase, the survey phase, the audit phase and the reporting phase. At the inception of the internal audit program, the first two phases are critical. As errors are identified, certain components of the planning and survey phases should be revisited to ensure that a pattern of errors does not develop that might expose the organization to substantial post-payment liability. The relevant aspects of each phase are detailed as follows.

The planning phase

While the guide describes a number of tasks relevant to this phase, three are critical. These include: (1) identification of risk areas; (2) analysis of relevant criteria; and (3) determination of the scope of the organization's audit program. Of these three, criteria analysis is the most important. To better understand your organization's risk areas and the scope of the audit program, you have to know which rules you might violate. Criteria analysis is nothing more than gathering the laws, regulations, contracts, and policies that affect or address the services performed in your organization. Auditors often rely on their experience and beliefs about what is right or wrong. Many times, these beliefs come from other billers, providers, or consultants, or just because "that's the way we have always done it." An auditor should never rely on such criteria. Instead, the auditor should seek out and read the actual statute, regulation, contractual provision, or policy at issue and objectively apply the criteria as written when performing the audit.

As an example, assume your organization uses a licensed practical nurse (LPN). There are a number of potential issues related to this topic alone: What is that person's scope of organization? Must a physician initiate care before the LPN can evaluate or become involved with a patient? How often must the physician follow up with or see the patient? Does the physician have to countersign the LPN's notes? To obtain the answers to these questions and many others, the auditor must first identify all of the rules associated with this aspect of the organization. Get the written rules and review them. State licensure statutes and regulations are a good place to

start. Once you know what the licensure boards permit, you also must consider the rules of each health plan you bill. You will likely find some differences. Just because a provider may legally perform a service does not mean that a health plan must pay for it or that a health plan's policy will permit you to bill for it. This is especially true when a provider is participating and there is a contractual agreement at issue. Beyond the terms of the contract, which may or may not be relevant to a particular issue, there are likely individual health plan medical policies and billing or documentation guidelines to consider.

Most physicians approach compliance as a necessary evil, or possibly even as a goal that the organization must achieve. It is neither. Compliance is a process, not a result.

For instance, when dealing with Medicare contractors, you'll find statutory requirements in the Social Security Act, a host of federal regulations written by HHS and CMS, CMS Manuals and various other Medicare documents issued by CMS, and the local coverage determinations published by the local Medicare contractor. For commercial health plans, you often can access medical policies and billing guidelines on the provider page of their Web site. For state licensure statutes and regulations, these can generally be referenced on the state Web site for the appropriate licensure board. While performance of a proper criteria analysis is often the most time-consuming aspect of any audit, it will be the most beneficial part of the process to the auditor and the organization. It is illuminating to find out what you didn't know – both good and bad. To the extent that interpretation of the relevant statutory, regulatory, contractual, or policy references may be beyond your capability, consider identifying and retaining an experienced health law attorney.

Once you have gathered and reviewed the appropriate criteria, you will be in a better position not only to know what your risk areas likely are, but also to define the scope of the audit. The scope will include identification of the type of audit (concurrent, retrospective, or a combination of both), as well as frequency of your audits. Concurrent audits occur prior to submission of claims data for payment. Retrospective audits will occur after claim submission and payment. Errors identified in a retrospective audit may require disclosure and a refund to the health plan. Initially, an audit should be conducted at each billing cycle. Once the error rate diminishes to an acceptable level, you can consider performing less frequent audits.

The survey phase

The guide describes this phase as assembling information about the organization that will permit refinement of your audit objectives and identification of specific audit areas. These issues should include the obvious errors such as whether the date of service is correct, the correct provider is identified on the claim, or the correct subscriber policy ID or group number is indicated, to name but a few. Additionally, the checklist should include items such as whether the service is coded properly, the units or modifiers reported are justified, the correct diagnosis code is reported, the Current Procedure Terminology® (CPT®) and ICD-9-CM codes are supported by the provider's documentation, and the documentation is legible and complies with the health plan's documentation standards.

Constructing your audit checklist requires identification of your risk areas based on a diligent review of all available criteria. You'll refine this checklist as your audit program proceeds. Items never in error might be evaluated on a diminished schedule or dropped altogether. Where errors are identified, these issues will be added to the checklist, if not listed already, or will be audited at a higher frequency until the effectiveness of your corrective action measures can be verified. Because of the potential for change, be certain to revisit the survey phase after your audit program begins to ensure the continued effectiveness of your audit program.

The audit phase

This phase involves the performance of the audit itself; however, there are standards that apply here as well. During the audit, be certain to evaluate all available information. The guide defines four types of evidence that should be considered when conducting an audit. Appropriate evidence may include physical proof from direct observation of the activity (often not possible), documentary evidence such as is contained in the clinical chart, testimonial evidence from the patient or provider as to what may be unclear or missing in the documentation, and analytical evidence, which may include analysis of the provider's billing profile or other statistical reports. Inclusion of evidence beyond the chart is consistent with the "information" requirements of Social Security Act §1833(e) (42 U.S.C. §1395(e)) (requiring the provider to furnish sufficient "information as may be necessary to determine the amounts due..."). While the Social Security Act generally only applies to Medicare claims, this standard is useful for determining the appropriateness of your billings in most audits. You should exercise care, however, to ensure that an individual commercial health

plan does not mandate strict "documentation" requirements as a condition of payment. Where such criteria exist, conformance with these criteria must be validated during your audit phase.

Having considered all appropriate information, a proper audit result exhibits a number of key characteristics. These include a statement of the criteria (what should be), a statement of the condition (the factual finding), where the condition differs from the criteria (error), and the cause of the error. Identifying the cause of the error is critical to developing recommendations to prevent such errors on future claims.

The reporting phase

This phase serves several important purposes. First, memorializing your findings provides evidence that you are performing internal audits. When required by your compliance program, it is important to have evidence that you are following the requirements of that program. Second, because a proper report details not only the errors found, why the error occurred, and the specific criteria violated, the audit report can serve as an educational tool. Finally, the audit findings will help the auditor to refine the risk areas in the planning phase and the audit objectives defined in the survey phase for future audits. When the organization discovers an error, the auditor should give that issue elevated scrutiny for future audits so that the effectiveness of corrective action measures may be evaluated.

An effective audit program is necessary to ensure not only that the organization gets paid the correct amount, but also that it can justify its right to keep the money.

Putting it all together

As is evident, the conduct of a proper audit involves more than a casual scan of a few claims during each billing cycle. To ensure the effectiveness of the audit, significant focus must be placed in the initial planning and survey phases to ensure that all relevant risk areas and issues are identified. While an audit will not catch every error, it should catch all of the errors likely to cause post-payment trouble if you have identified all of the key risk areas and issues.

To identify your key risk areas and issues, be certain to collect and review all of the relevant statutes, regulations, contracts, and policies that would detail the standards by which your claims will be evaluated. After collecting this material, read it! This information will not help you if it stays on a shelf. The key to performing an objective audit is challenging everything you believe to be true and reading the relevant criteria – each time you perform an audit. You might be amazed by how your understanding of a particular policy will change, even if you have read the policy many times, when you apply that policy to a new set of facts. If necessary, engage a qualified health law attorney to assist in the process of collecting and interpreting this information. The expense is often well justified because an attorney experienced in dealing with post-payment issues is likely to have a better idea of what your risk areas are than you will.

Your review and understanding of the relevant criteria will help you identify errors that might result in inappropriate payments as well as errors that result in underpayment. While there is generally no civil or criminal false claims liability for undercoding, organizations often lose substantial revenue by trying to manage their post-payment risk by under-reporting services. Also, be vigilant to review not only what was reported but also what was not. Undercoding and omissions are just as likely to attract post-payment attention as over-coding. Making sure your claims are correct is the only sure-fire way to avoid post-payment liability.

Ultimately, right is right and wrong is wrong. The key is being able to identify the difference. If you think you know the difference, challenge yourself to find the appropriate criterion that proves you right. Does your impression of right versus wrong change based on the health plan you are billing? You will be surprised by how often it does. Implementation of an effective auditing program will eliminate the guesswork in your billing process by identifying errors prior to claims submission so that you can get them corrected. After the audit, you can use what you have learned to educate providers and staff to prevent recurrence of those errors in the future. While it takes a bit of effort, only after implementing a structured audit process can you reasonably assure yourself that you have a compliant billing operation.

Michael Miscoe, CPC, CHCC, CRA, is a 1985 graduate of the United States Military Academy, a Certified Professional Coder, Certified Healthcare Compliance Consultant, and the President of Practice Masters, Inc. He has more than 17 years of billing experience and 11 years of consulting experience with a wide variety of health care provider specialties. He is a qualified Independent Review Organization and provides expert analysis related to civil and criminal false claims cases. He is a current member of the National Advisory Board of the American Academy of Professional Coders (AAPC). The AAPC provides certification and education to medical coders in physician offices, hospitals, and outpatient centers. For more information, visit the AAPC's Web site at www.aapc.com.

Tax-Exempt Organizations

IRS answers questions about EHR subsidies

by Hilary Goehausen, Contributing Editor

The IRS has released a series of questions and answers on its Web site intended to clarify the Exempt Organization (EO) Division's May 11, 2007, field directive applicable to tax-exempt hospitals that provide medical staff physicians with electronic health record (EHR) subsidies.

The directive declared that the IRS will not treat EHR subsidies provided by hospitals to medical staff physicians as impermissible private benefit or inurement so long as the benefits are permitted under HHS regulations. While the directive had been prepared to allay hospitals' concerns that providing EHR subsidies to their staff physicians would raise exemption issues, it succeeded only in raising further questions and concerns from many hospitals in search of additional assurances.

Six questions and answers, which can be found on the IRS Web site (www.irs.gov/pub/irs-tege/ehr_qa_062007.pdf), provide the following additional information to clarify the May EO directive and reassure hospitals that no hidden traps have been set:

- *Financial assistance and subsidies.* The terms "financial assistance" and "subsidies" used in the directive refer to arrangements in which the hospital provides a physician with EHR-related software, information technology, or training services, and the physician contributes a portion of the cost. The terms are consistent with HHS regulations and do not refer to cash payments from hospitals to physicians.
- *Consistent conditions.* If a hospital's EHR subsidy arrangement is not entirely consistent with the conditions set forth in the IRS' directive, the arrangement will not be covered by the safe harbor described in the directive. However, this does not necessarily mean that the arrangement will produce impermissible private benefit or inurement. An IRS agent will look at "all the facts and circumstances" surrounding the arrangement.
- *Disqualified persons.* Assuming that a hospital meets all the conditions set forth in the IRS' directive, an IRS agent will not treat a Health Information Technology Subsidy Arrangement provided to an Internal Revenue Code §4958 "disqualified person" as an excess benefit transaction.
- *Inurement outside EHR arrangements.* If an IRS agent finds that the net earnings of a hospital have inured to the benefit of one or more staff physicians outside the context of an EHR arrangement, the hospital will not be covered by the directive's safe harbor provision. A determination of whether the arrangement itself produces impermissible private benefit or inurement, however, will require inquiry into all the facts and circumstances surrounding the arrangement.
- *Access restrictions.* A staff physician may deny a hospital access to patient records if the access would violate federal and state privacy laws or a physician's contractual obligations to patients. Also, a hospital and staff physician may establish "reasonable conditions" relating to the hospital's access.
- *Access availability.* A hospital may provide access to its Health Information Technology Items and Services to various groups of physicians at different times according to criteria related to meeting the health care needs of the community. ■

CCH Washington Bureau, June 25, 2007.

Quality of Care

Health care quality shows improvement under Executive Order

by Valerie L. Witmer, J.D., Contributing Editor

Significant steps toward widespread health care quality and price reporting have been achieved since President Bush issued Executive Order 13410 last year, according to HHS Secretary Michael Leavitt. Leavitt released summaries of four federal departments and agencies' efforts to satisfy the presidential directive and announced that "[i]n its first year, the President's Executive Order has begun to have a culture-changing effect in the health care sector."

According to HHS, the Executive Order mandated action for federal agencies centered on four "cornerstone goals:"

(1) connecting the system through the adoption of interoperable health information technology;
(2) measuring and making available results on the quality of health care delivery;
(3) measuring and making available price information on the costs of health care items and services; and
(4) aligning incentives so that payers, providers, and patients benefit when care delivery is focused on achieving the best value of health care at the lowest cost.

First-year results. Leavitt reported that substantial progress has been made toward improving health care quality and affordability in the first year of the Executive Order. HHS has successfully piloted models for a Nationwide Health Information Network and will begin trial implementations in 2008. Federal departments and agencies are working to adopt consistent contract language that will require the use of newly developed interoperability standards.

In June 2007, CMS expanded quality reporting measures by adding mortality measures for heart attack and heart failure and plans to add patient satisfaction measures in 2008. CMS also has begun collecting quality information upon which it will base bonus payments to be paid to participating physicians in mid-2008.

"For the first time, we are working effectively together to make possible reliable and consistent measures of quality and price", Leavitt said. "This is the foundation we must have for a future of affordable, effective, and high quality health care." ■

HHS Press Release Aug. 23, 2007.

Medicare

Amended lab CoPs address HCV-infected blood products

by Matthew Mann, J.D., Contributing Editor

The Medicare conditions of participation (CoPs) applicable to hospital laboratories have been amended to specify the steps hospitals must take when they become aware that they may have administered blood or blood components infected with the hepatitis C virus (HCV). The interim final rule issued by CMS on August 24, 2007, amends current regulations that implement similar steps for blood products potentially infected with the human immunodeficiency virus (HIV) (*see* 42 C.F.R. §482.27(c)).

In accordance with §1861(e) of the Social Security Act, hospitals must meet certain conditions to participate in the Medicare program. These CoPs are intended to protect patient health and safety and ensure that high-quality care is provided. Hospitals receiving payment under Medicaid must meet the Medicare CoPs.

Under the amended Medicare CoPs for laboratory services (42 C.F.R. § 482.27(c)), hospitals that transfuse blood and blood components must: (1) prepare and follow written procedures for appropriate action when it is determined that blood and components they received and transfused are at an increased risk for transmitting HCV; (2) quarantine prior collections in inventory from a donor who is at an increased risk for transmitting HCV infection; (3) notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and (4) extend the records retention period to ten years. In addition, the amended regulations establish a cut-off date of August 24, 2015, for retrospective HCV lookbacks.

The changes are based on recommendations by the Secretary's Advisory Committee on Blood Safety and Availability and have been published in conjunction with a Food and Drug Administration final rule (72 FR 48766, Aug. 24, 2007). The interim final rule will be effective February 20, 2008.■

Interim final rule, 72 FR 48562, Aug. 24, 2007, Health Care Compliance Reporter ¶700,045.

In the News

Drug company settles FCA claims for $190 million

Aventis Pharmaceuticals Inc. has paid the U.S., several states, and the District of Columbia over $190 million to resolve allegations that the company caused false claims to be filed with Medicare and other federal health programs as a result of the company's alleged fraudulent pricing and marketing of drugs, the Department of Justice (DOJ) announced. The government alleged that Aventis engaged in a scheme to set and maintain fraudulent and inflated prices for Anzemet, an antiemetic drug, knowing that federal health care programs established reimbursement rates based on those prices. Of the $190 million settlement, the federal recovery is $179,787,726, and the states and District of Columbia's recovery for their share of Medicaid is $10,645,600. Aventis also agreed to enter into a Corporate Integrity Agreement with the HHS Office of Inspector General that will require the company to report accurate average sales prices and average manufacturer's prices for its drugs covered by Medicare and other federal health care programs.

DOJ Press Release, Sept. 10, 2007.

Bill would require drug companies to disclose payments to doctors

Large drug manufacturers would be required to disclose the gifts they give to physicians under a newly introduced bill – the "Physician Payments Sunshine Act" (S. 2029). The bipartisan bill from Sens. Charles Grassley (R-Iowa), and Herb Kohl (D-Wisc.) would require manufacturers of pharmaceutical drugs, devices and medical supplies to disclose the amount of money they give to doctors through payments, gifts, honoraria, travel and other means. Kohl cited estimates that 94 percent of doctors have received gifts from drug companies totaling $19 billion. The bill is designed to apply only to the largest manufacturers; only manufacturers with $100 million or more in gross revenue would be required to comply with the legislation. Companies that fail to report could face penalties ranging from $10,000 to $100,000 for each violation.

S. 2029, 110th Cong., 1st Sess. (2007); CCH Washington Bureau, Sept. 10, 2007.

ASC proposed rule targets quality of care

A proposed rule issued on August 24, 2007, would update the existing ambulatory surgical center (ASC) conditions of coverage to reflect contemporary standards of practice in the ASC community, as well as recommendations from the HHS Inspector General. The new requirements will promote and protect patient access to quality services in ASCs. Proposed rule changes include: (1) a more comprehensive quality assessment and performance improvement (QAPI) condition; (2) a requirement that the ASC's governing body be responsible for the oversight and accountability for the updated QAPI program; (3) a new patient rights condition to address disclosure of physician financial interests in the ASC, advance directives, the grievance process, and confidentiality of clinical records; and (4) a comprehensive patient assessment requirement to ensure that accurate and thorough assessments are conducted to assure appropriate and safe surgery.

CMS Press Release, Aug. 24, 2007.