G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Cytology Coalition Urges Legislative Reform

A major cytology coalition has called on the Clinical Laboratory Improvement Advisory Committee (CLIAC) to adopt a legislative solution to change CLIA (Clinical Laboratory Improvement Amendments) gynecologic cytology proficiency testing, saying the currently regulatory route is going nowhere.

Speaking before CLIAC on September 5 on behalf of the Cytology Proficiency Improvement Coalition, which includes 60 national and state organizations, George Birdsong, MD, said that while the panel's efforts to advance regulatory recommendations "have been appreciated, we believe enactment of H.R. 1237, the Cytology Proficiency Improvement Act of 2007, is a better approach." The legislation was introduced in the House earlier this year; there is as yet no Senate counterpart.

Dr. Birdsong, who is director of anatomic pathology at Grady Health System in Atlanta and associate professor of pathology and laboratory medicine at Emory University School of Medicine, noted that H.R. 1237 would:

- Suspend the current proficiency testing program effective upon enactment;
- Substitute a requirement that labs ensure that all individuals involved in screening and interpreting Pap tests participate annually in a continuing medical education (CME) program that tests their locator, recognition, and interpretive skills;

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CMS to Expand Medicare Audit Program

A major expansion of the audit program that uncovers and reconciles inaccurate Medicare claims payments is under way at the Centers for Medicare and Medicaid Services (CMS).

Connie Leonard, project officer for the Recovery Audit Contractor (RAC) program, said August 27 that CMS will employ a staggered approach to spreading the three-state program nationwide.

Addressing a meeting of the Practicing Physicians Advisory Council (PPAC), an agency board composed of physicians, Leonard said that CMS first is focusing the expansion on hospital claims, which make up most of the improper payments. Other providers will be included by March 2008.

Congress authorized the RAC demonstrations in the Medicare

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- Require that the CME program be approved by the Accrediting Council for Continuing Medical Education for the American Academy of Continuing Medical Education; and
- Require the lab to maintain a record of the cytology CME results of each individual. Accrediting organizations will inspect these results during regular lab inspections required by CLIA.

"The repeated delays and the absence of even a draft or proposed regulation, in our view, demonstrate how untimely and ineffective the regulatory process is for updating professional standards," Dr. Birdsong said. "For example, by our projection, the process of revising the cytology PT rules that began in 2006 will likely not be completed until 2009, meaning at least five years will have elapsed since the profession began requesting changes to the regulation in 2004." Moreover, CMS has ruled out any proposed changes to the CLIA statute.

ACLA, CAP Advocate Separate 'Lab Seat' in New E-Health Entity

As the Department of Health and Human Services (HHS) prepares to shift responsibility for development of a nationwide exchange system for personal e-health records to a new public-private partnership, the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP) are urging that laboratory services be given a separate seat in the entity that will succeed the American Health Information Community (AHIC).

This is a chance to "correct the wrongs of the past," says Jason DuBois, ACLA vice president of government relations. He notes that labs had sought their own representation on AHIC before its primary members were chosen, but in the end were lumped with pharmacy under "ancillary services."

AHIC is a federally chartered advisory committee, formed in 2005, that provides guidance to HHS on how to make health records digital and interoperable and how to assure that the privacy and security of those records are protected. The charter requires that its responsibilities be transferred to a public-private entity. HHS invited comment on this transfer in an August 2 *Federal Register* notice and issued a final white paper on August 7 describing its expectations for the member-supported partnership.

In comments submitted September 10, ACLA emphasized: "Lab data are the 'keystone' to the medical record—electronic or otherwise. . . . With 60% of data in medical records derived from lab test results, every community that is trying to launch some health IT infrastructure is looking at labs as the first element they need." Labs also confront unique liability issues that require expertise on CLIA rules and state law that impose restrictions on use and disclosure of protected health information that no other healthcare sector faces, ACLA added.

In its comments submitted September 10, CAP said a separate membership sector for clinical labs, like that proposed for pharmaceuticals and devices, would permit a vital interface with other physicians. "Pathologists have an important perspective and indispensable role to play in identifying what information from diagnostic testing should be included in e-health records and how that information should be transmitted to maximize its use in clinical decision making."

The AHIC successor entity will include representatives from federal and state governments and from the private sector. But getting some of its costs underwritten by federal departments and agencies like HHS, CMS, CDC, the FDA, and others will be crucial, says DuBois. "It won't have the impact intended if it's just private."

Former Tenet Lawyer Charged With False Certification

A complaint filed in federal district court in Florida alleges a former general counsel of Tenet Healthcare Corp. violated the False Claims Act (FCA) by submitting false certifications to Medicare, the Department of Justice (DOJ) announced September 18 (*United States v. Sulzbach*).

The complaint, filed in the U.S. District Court for the Southern District of Florida, contended that in June 1997 and June 1998, Christi Sulzbach, then associate general counsel and corporate integrity program director at Tenet, submitted false certifications to the Department of Health and Human Services.

According to the complaint, Sulzbach falsely stated that, to the best of her knowledge and belief, Tenet was in material compliance with all federal program legal requirements.

Sulzbach's false declarations allowed Tenet to bill Medicare for millions of dollars in claims that it was not legally entitled to receive under the Stark statute, the complaint said. Sulzbach's false declarations also obstructed the government's discovery and recoupment of millions of dollars of improper payments that Tenet had received already, the complaint added.

According to the complaint, Sulzbach falsely stated that, to the best of her knowledge and belief, Tenet was in material compliance with all federal program legal requirements.

Illegal Billing

The complaint alleged that in early 1997, Sulzbach learned that a Tenet-owned hospital, North Ridge Medical Center, in Fort Lauderdale, Florida, illegally billed Medicare for referrals from certain employee physicians whose contracts violated the Stark statute. Sulzbach directed Tenet's outside counsel to investigate, and outside counsel confirmed that some of the physician employment contracts were illegal.

In May 1997, a Tenet employee, Sal Barbera, filed an FCA qui tam action against Tenet that alleged the physician employment contracts at issue were illegal. After investigating, the government eventually settled the claims with Tenet for $22.5 million.

The complaint alleged that, throughout the process, Tenet's legal team, under Sulzbach's personal direction, consistently denied that the physician employment arrangements at issue violated the Stark statute. The statute prohibits hospitals from billing Medicare for referrals from physicians with which the hospitals have financial relationships unless those relationships meet certain strict conditions, the DOJ press release said.

Tenet entered into a settlement with the government in 2006 to resolve a variety of claims that the hospital chain defrauded and overcharged the Medicare program and Tenet agreed to pay the government $920 million, the complaint said.

Tenet also agreed to produce various documents that had been withheld as privileged, including a small number of documents related to the Barbera FCA qui tam case, which established that Sulzbach knew that her declarations were false when she made them, the complaint contended.

Although the government entered into a settlement with Tenet relating to the physician contracts, that agreement did not release Sulzbach's liability, the release said.

The FCA qui tam action will be litigated jointly by DOJ's Civil Division and the U.S. Attorney's Office for the Southern District of Florida.

CMS Sets Criteria for Naming MIPS Contractors

The Centers for Medicare and Medicaid Services (CMS) has finalized criteria for selecting Medicare Integrity Program (MIP) contractors and certain provisions pertaining to Medicare administrative contractors.

The final rule was published in the August 24 *Federal Register* and becomes effective October 23. CMS initially proposed the MIP contracting provisions June 17, 2005. The rule defines the types of entities eligible to be awarded MIP contracts and clarifies that Medicare administrative contractors (MACs) are eligible to perform MIP functions in certain circumstances.

Likewise, the rule describes procedures for awarding and renewing MIP contracts and specifies the types of functions MIP contractors may perform.

The Medicare Integrity Program was established by Congress in the Health Insurance Portability and Accountability Act of 1996, which gave CMS the authority to contract with certain entities to perform program oversight functions such as medical and utilization reviews, claims reviews, cost report audits, overpayment recoveries, and provider education.

CMS said in the final rule that MIP contractors also could develop prior authorization lists for durable medical equipment items and to conduct Medicare secondary payer activities.

CMS Streamlining Integrity Efforts

The Centers for Medicare and Medicaid Services (CMS) is creating a program that will divide the country into seven zones that will be targeted for increased scrutiny, Kimberly Brandt, program director of the Program Integrity Group at the Centers for Medicare and Medicaid Services (CMS), said September 24.

The changes reflect new program integrity efforts at CMS that focus on three areas: a new contracting strategy, increased field presence, and rapid response teams, she said in a presentation at the Fraud & Compliance Forum, sponsored by the American Health Lawyers Association and the Health Care Compliance Association.

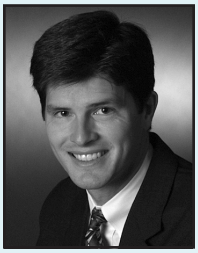
Under the new contracting strategy, CMS is defining seven zones that will address fraud "hot spots" and integrates Medicare fee-for-service and Medi-Medi program integrity functions. (The Medi-Medi program is a data match program in 10 states that matches Medicare and Medicaid claims data.) "This strategy achieves the best value for CMS by leveraging economies of scale and concentrating on high-fraud areas," Brandt said. The new name for the zone contractors are Zone Program Integrity Contractors (ZPICs).

Under the second prong of the integrity strategy, CMS field offices will play an increased role, as they provide "additional, on-the-ground efforts to deter, detect, and report fraud, waste, and abuse in high vulnerability areas of the country," Brandt said. Citing successes of field offices, Brandt said the Los Angeles office has identified about $2.1 billion in improper payments, and the Miami office has done anti-fraud work in the infusion services industry, resulting in about $1.8 billion in savings to the Medicare Trust Fund.

Under the third prong of the program, CMS is using rapid response teams—teams of Medicare and Medicaid central office and field office staff—to identify, address, and prevent fraud in emerging hot spots. This involves sharing resources across field offices to address "flare ups" in other field office territories, Brandt said. She said the ZPICs will support the field offices and the rapid response teams in special fraud initiatives.

COMPLIANCE PERSPECTIVES

Stark II, Phase III: Changing the Compliance Landscape



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The Centers for Medicare & Medicaid Services (CMS) continues to change the compliance landscape facing pathologists, radiologists, and other physicians, as well as hospitals, laboratories, and imaging providers. On Sept. 5, 2007, CMS published the long-awaited Phase III final regulation under the Stark physician self-referral law (*See 72 Fed. Reg. 51,012*). The changes are different from (although somewhat related to) the changes in the proposed 2008 Medicare Physician Fee Schedule (MPFS), published July 12, 2007 (*See 72 Fed. Reg. 38,122*). While the MPFS changes were only proposed, the Phase III changes are final and become effective Dec. 4, 2007.

The Phase III regulation contains some important changes. CMS also made statements in the preamble to the Phase III regulation that are not labeled changes, but have the practical effect of changing commonly held views of how the Stark law operates. These changes and "clarifications" will require reconsideration and possibly renegotiation of thousands of existing arrangements.

Recruitment and Retention Exceptions

CMS clarified the physician recruitment exception to allow hospitals to impose reasonable credentialing restrictions on physicians whom they recruit. These restrictions cannot take into account "in any way" the volume or value of referrals or other business generated. This leaves open the question of whether hospitals may impose minimum procedure requirements for quality-of-care purposes. CMS specifically refused to take a position on economic credentialing.

CMS issued considerable clarification to the relocation requirements under the recruitment exception. CMS clarified that the recruited physicians must relocate their practice from outside hospital's Geographic Service Area (GSA) to inside the hospital's GSA. The relocation requirement also requires recruited physicians to move their medical practice 25 miles or have a new medical practice that derives at least 75% of its revenues from professional services furnished to patients not seen or treated by the physician during the preceeding three years. CMS created greater latitude for physicians who, for two years immediately prior to recruitment, had no separate private practice and were employed on a full-time basis to serve patients of (i) federal or state prisons; (ii) the Department of Defense or Department of Veterans Affairs; and (iii) Indian Health Service facilities.

CMS provided flexibility under the "zip code rules" for defining the hospital's GSA. The basic rule is that the hospital's GSA is the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. In Phase III, CMS created a new rule for relocating a physician to a zip code "hole" that would not otherwise be part of the hospital's GSA. The zip code hole rule is available where no inpatients reside in the zip code, but the zip code is entirely surrounded by zip codes in the GSA. CMS also has created an exception in circumstances where all of a hospital's contiguous zip codes do not account for 75% of the inpatients. CMS created an alternative zip code rule for certain rural hospitals to allow them to use certain noncontiguous zip codes.

CMS clarified that a hospital may use any configuration of zip codes that meets the regulatory requirements at the time the parties enter into the recruitment arrangement. CMS added that a hospital may use different zip code configurations for each recruitment arrangement even if the arrangements are entered into on the same date.

Phase II limited the overhead costs that can be allocated to a recruited physician to "actual, additional incremental costs" attributed to the recruited physician. Despite many requests, CMS generally declined to permit other cost-allocation methods, citing potential abuse of the program. However, CMS added some flexibility where physicians are relocating into a practice in a rural area or health professional shortage area (HPSA) to replace a physician who has left the practice within 12 months because the physician retired, relocated outside the hospital's GSA, or died. In such cases, a per capita allocation of overhead may be used so long as it does not exceed 20% of the practice's aggregate cost.

CMS modified its position with respect to practice restrictions, allowing noncompete clauses to the extent that they do not "unreasonably restrict the recruited physician's ability to practice medicine" in the hospital's GSA. CMS indicated that liquidated damages provisions would be acceptable so long as the amount was not unreasonable or otherwise had a substantial effect on the physicians remaining in the hospital's GSA.

CMS expanded the retention exception by eliminating the requirement of a written offer and permitting the use of *bona fide* opportunities for future employment. The physician must provide written certification to support the *bona fide* opportunity. In addition, the hospital must take reasonable steps to verify that the employment opportunity requires the physician to relocate outside of the hospital's GSA. Retention payments are limited to 24 months. CMS clarified that the amount of a retention payment is not limited to the cost of recruiting a new physician but rather to a physician who is new to the hospital's GSA. Retention payments may take into account the physician's experience, training, and length of service in the area.

Office Space and Equipment Rental Exceptions

While Phase III did not make any changes to the office space or equipment rental exceptions, CMS added some clarifications. CMS indicated that parties may amend lease agreements during the first year as long as no change is made to the rental charge. Such amendments do not require the agreement to be extended for an additional year. If the parties wish to change any lease term that is material to the rental charges, including the amount paid, the amount of space leased, or type of equipment rented, CMS advised that the existing agreement should be terminated and a new agreement entered into. The new agreement may not begin until the first year of the original lease is complete. CMS stated that the fair market value exception is not applicable to office space or equipment leases.

With respect to office-sharing arrangements, CMS emphasized that a lessee must have exclusive use of the leased space or equipment, with the exception of common areas. CMS stated that exam rooms are not common areas. In the preamble, CMS did not distinguish between block leases, which are typically exclusive use arrangements, versus cost-sharing arrangements, where physicians typically share space, equipment, and costs on a nonexclusive basis.

CMS clarified that lessors may charge a premium for holdover terms, provided such premiums are set in advance and do not take into account the volume or value of referrals or other business generated by the parties. CMS declined to extend the holdover period beyond six months in cases where a landlord is trying to evict a tenant.

Personal Services Exception

CMS included a six-month holdover provision to the personal services exception similar to the provision under the office space and equipment rental exceptions. CMS also stated that amendments to the compensation paid under a personal services agreement should be accomplished by terminating the existing agreement and entering into a new agreement.

Nonmonetary Compensation Exception

Phase III contains a new repayment provision that permits a physician to repay certain amounts that exceed the limit under the nonmonetary compensation exception (currently $329). The amount repaid may not exceed 50% of the limit. In addition, the physician must repay the excess within the same calendar year it was provided or 180 days, whichever is earlier. This new repayment provision may be used only once every three years per referring physician.

CMS added a provision allowing entities with formal medical staffs to provide one "local medical staff appreciation event" per year that does not count toward the non-monetary compensation limits. The provision does not apply to laboratories because they do not have formal medical staffs.

"Stand-in-the-Shoes"

In Phase III, CMS added a "stand in the shoes" provision to the definition of direct compensation arrangements so that arrangements between designated health service (DHS) entities and group practices are treated as arrangements between the DHS entity and the individual physicians in the group. Consequently, such arrangements can no longer rely on the indirect exception. CMS also revised the definition of "physician organization" to include a physician practice; a physician group practice; or a professional corporation, of which the referring physician is the sole owner. CMS did not include corporations, limited liability companies, or partnerships unless they are physician practices or group practices.

Recognizing that many existing arrangements had been structured to comply with Phase II, CMS created a grandfather provision. The provision is limited to arrangements in existence prior to the publication date of Phase III (Sept. 5, 2007) that comply with the Phase II indirect compensation arrangement exception and need not be amended during the original term of the arrangement *or* the current renewal term.

Group Practice (Physician in the Group, Reassignment, and "Incident To" Services)

In prior Stark regulations, CMS drew a distinction between physicians who are "members of the group" (owners, employees, and *locum tenens* physicians, but not independent contractors) and "physicians in the group" (members and independent contractors).

In Phase III, CMS modified the definition of "physician in the group" to require an independent contractor physician to furnish patient care services for a group under a contractual arrangement *directly* with the group. CMS stated in the preamble that the arrangement may not be between the group practice and another entity, such as a staffing company. CMS also emphasized that independent contractor physicians are considered "physicians in the group" only when performing services in the group practice's facilities.

In Phase III, CMS adopted the definition of "incident to" services under the Medicare billing rules and clarified that the definition applies to both services and

Fair Market Value

In Phase II, CMS created a "safe harbor" under the fair market value definition for hourly payments for physician services determined using the average hourly rate for emergency room physicians in a relevant market or certain national physician compensation surveys. Based on concerns about the impracticability of meeting the "safe harbor" and the negative inference on payments not meeting the safe harbor, CMS eliminated the safe harbor.

supplies. CMS also modified its position regarding compensating physicians in the group through profit shares or productivity bonuses based on "incident to" services. For profit sharing, CMS now takes the position (in a change from Phase II) that profits must be allocated in a manner that does not *directly* relate to DHS referrals, including any DHS billed as "incident to" services.

Under Phase II, CMS had permitted profit sharing based directly on "incident to" DHS services. For productivity bonuses, CMS continues to permit such payments to be based *directly* on services that the physician personally performed and services "incident to" such personally performed services (even if those "incident to" services are otherwise DHS).

Intra-Family Rural Referral Exception

Phase III expanded the intra-family rural referral exception to provide an alternative distance test based on transportation time from the patient's residence. Under the new provision, a physician may qualify to make an intra-family rural referral if timely DHS is needed and cannot otherwise be provided within 45 minutes transportation time from the patient's residence. CMS recommended that physicians retain mileage or driving-time information from independent sources, such as on MapQuest and, if relevant, published weather reports.

Referrals and DME

CMS previously concluded that services personally performed by the referring physician did not constitute a referral and did not have to satisfy a Stark exception. In Phase III, CMS did not change the definition of "referral" but concluded that it was practically impossible for a physician to personally furnish durable medical equipment (DME). According to CMS, a physician would have to be enrolled as a Medicare DME supplier and personally perform all of the duties of a DME supplier to furnish DME. CMS specifically stated that continuous positive airway pressure equipment ("CPAP") is DME that does not qualify for the in-office ancillary services exception.

Academic Medical Center Exception

In Phase III, CMS clarified that the compensation paid to a physician must meet three criteria to fall within the AMC exception: 1) compensation paid by each component of an AMC must be set in advance; 2) compensation paid by each component must not take into account the volume or value of referrals; and 3) the *aggregate* compensation of all academic medical center components cannot exceed fair market value. CMS emphasized that the exact amount paid by each component need not be established in advance, but any formula or methodology must be "set in advance." CMS recognized that the compensation paid by each component of an AMC does not have to be fair market value as long as the aggregate amount paid by all AMC components is fair market value.

Phase III revised the definition of "academic medical center" to clarify that individual physicians with the same class of privileges must either be included or excluded for purposes of determining whether a majority of physicians on an affiliated hospital's medical staff are faculty members of the affiliated medical school.

Compliance Training Exception

CMS reversed its position to permit DHS entities to provide physicians and their office staff with compliance training where continuing medical education ("CME") credit is available, although only where "compliance training is the primary purpose of the program." CMS also clarified that hospitals may provide compliance training online under certain circumstances.

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Medicare Audit Program, *from page 1*

Prescription Drug, Improvement, and Modernization Act of 2003. The three-year project has continued for providers since March 2005 in Florida, California, and New York. In fiscal year 2006, the three contractors for the demo collected $68.6 million in overpayments and paid out $2.9 million in underpayments.

With the intention of promoting Medicare program integrity efforts, the Tax Relief and Health Care Act of 2006 made permanent and expanded the RAC program to all states by 2010.

Under the demo, the RACs are able to mine data four years back from the date the claim was paid. Under the permanent program, this was reduced to three years.

Adding Three States

As the first phase of the expansion, CMS will add one more state to the existing RAC contracts. The RAC contract for Florida will add South Carolina, the one for New York will add Massachusetts, and the one for California will add Arizona, she said. Four more RACs will be hired by early 2008.

Under the demo, the RACs are able to mine data four years back from the date the claim was paid. Under the permanent program, this was reduced to three years.

The majority (77%) of improper payments in fiscal 2006 were from claims paid to inpatient hospitals. Physicians, grouped with ambulances and laboratories, comprised 6% of improper payments.

During the meeting, PPAC members recommended that CMS break out the payment modification data, so that doctors would know specifically their contribution. Council members in the past have asked that doctors be removed from the program because of the small percentage of payments that have stemmed from their claims.

Melanie Combs, CMS's RAC technical adviser, described the agency's "Improper Payment Prevention Plan" for doctors, gleaned in part from examples found in Florida. In fiscal 2006, $1.2 million in doctor overpayments were found for multiple surgeries that occurred during the same surgical session, and $420,000 in overpayments were found as a result of doctors billing for more units than were administered.

Prevention measures suggested by staff included encouraging carriers to educate physicians about coding rules and alerting contractors to potential pricing problems for particular claims.

Combs said that the information would be placed on the CMS Web site so that medical specialty societies could develop instructional articles for their members.

E&M Codes

Under the staggered approach for expansion, Combs said, the RACs will postpone, at least until March 2008, looking at some of the more complicated areas, such as evaluation and management codes that physicians use to code levels of office visits, as well as hospice and home health claims.

Combs said that CMS is in the process of trying to improve problems with the demo before the expansion, including clarifying and adding more detail to improper payment letters.

The council voted to recommend that CMS create clear and uniform notifications, with the objective of decreasing confusion and inefficiencies and increasing clarity and compliance.

Providers have been less than enthusiastic about the RAC demo. Earlier this year, Sen. Dianne Feinstein (D-CA)

asked CMS to look into complaints that a RAC contractor, PRG-Schultz International Inc., had denied almost all claims audited, that the company acted outside its authority, and that the procedures to appeal against overpayment assessments were burdensome.

During the PPAC meeting, Earl Berman, medical director for PRG-Schultz, praised the program for stabilizing provider reimbursement by returning improperly paid money to the Medicare trust fund and providing feedback to the regular CMS contractors that will help them reduce the error rate.

However, PPAC members recommended that CMS include questions about provider satisfaction levels with the RACs in the Medicare Contractor Provider Satisfaction Survey (MCPSS).

Unlikely Edits

On another claims auditing program, Brenda Thew, division director of CMS's Division of Benefit Integrity, said the agency is considering changing its stance on the confidential nature of its medically unlikely edits (MUEs) program.

The objective of the MUE program is to detect implausible claim submissions to avert inappropriate payments. CMS has said the program is necessary because the government spends billions of dollars on coding errors, a portion of which are typographical.

CMS has said that the intent of the program, previously called medically unbelievable edits, is to prevent the payment of obviously erroneous Medicare claims submissions, such as payment for milliliters of a product when the unit of billing is liters or billing for 60 services when the provider meant to bill for six services.

Thew said her division is querying carrier medical directors about possible disclosure and will start to get input from other divisions within CMS and other stakeholders about whether the edits should be released or whether requests for release should continue to be referred to CMS's Freedom of Information Act office.

PPAC recommended that the MUEs be made available to the public.

More information about the meeting is at *www.cms.hhs.gov/FACA/03_ppac.asp*.

FDA Clarifies Rules for Analyte-Specific Reagents

In industry guidance published in the September 14 *Federal Register*, the Food & Drug Administration announced the availability of updated Frequently Asked Questions about commercially distributed analyte-specific reagents (ASRs). A draft of the guidance was issued Sept. 7, 2006.

The latest version clarifies certain ASR rules and "eliminates confusion about particular marketing practices among ASR manufacturers," said the FDA's Center for Devices & Radiologic Health in releasing the revised guidance.

The FDA specifically noted that the guidance is not intended to cover the role of clinical laboratories in developing an array of genetic and other tests in-house. As noted in the guidance, "ASRs are building blocks of lab-developed tests."

The FDA alerts ASR manufacturers to two practices it sees as inconsistent with the marketing of an ASR:

- Combining, or promoting for use, a single ASR with another product, such as other ASRs, general purpose reagents, controls, designated lab instruments, software, and other products.
- Promoting an ASR with specific analytical or clinical performance claims, instructions for use in a particular test, or instructions for validating a specific test using the ASR.

When an ASR falls outside the definition in the rules, the FDA views the product as another type of in vitro diagnostic device (IVD) or device component not covered by the ASR rules and, therefore, not necessarily exempt from premarket requirements.

Major Revisions

In response to public comments on the earlier draft guidance, the FDA said it has revised the document to clarify that:

- The agency views ASRs as being intended to detect a single ligand or target.
- Oligonucleotide primer pairs and polyclonal antibodies can meet the definition of an ASR when properly marketed because they are for the identification of a single target or ligand (e.g., used to detect a single protein, a single nucleotide change, or a single epitope).
- When manufacturers provide labs with information describing use of their product in a specific test, the product would fall outside the definition of an ASR.

The labeling for Class I, exempt ASRs must bear the statement, the FDA says: "Analyte Specific Reagent. Analytical and performance characteristics are not established." Class II or III ASR labels must state: "Analyte Specific Reagent. Except as a component of the approved / cleared test (name), analytical and performance characteristics are not established."

To assist makers of Class II or III IVDs that are currently being inappropriately labeled and marketed as ASRs to come into regulatory compliance, the FDA intends to exercise enforcement discretion with respect to premarket approval and clearance requirements for 12 months.

The revised guidance is on the Center for Devices and Radiological Health (CDRH) Web site at *www.fda.gov/cdrh/oivd/guidance/1590.html*.

CMS Rule Aims to Reduce Transfusion Risk for Hepatitis C

The Centers for Medicare and Medicaid Services (CMS) has published an interim final rule establishing a series of requirements that are intended to reduce the risk of hepatitis C infection in the transfusion of blood and blood components.

About 4,980 Medicare and Medicaid participating hospitals will be affected by the rule. HCV infection is the most common chronic blood-borne infection in the United States.

The rule, published in the August 24 *Federal Register* with a comment period until October 23, will take effect Feb. 20, 2008.

The interim final rule, which adopts many requirements laid out in a November 16, 2000, proposed rule, directs hospitals and other facilities that transfuse blood and blood components to:

- Establish and maintain a written agreement with a regularly used blood bank governing procurement, transfer, and availability of blood and blood components;
- Quarantine prior collections from a donor who is at increased risk for transmitting HCV infection;
- Extend the time for maintaining adequate records of the source and disposition of all units of blood and blood components from five years to at least 10 years from the date of disposition; and
- Make reasonable attempts to notify a patient or the attending physician that they have received potentially HCV infectious blood or blood components when this occurs, as well as notify them of the need for HCV testing and counseling.

Medicare Targets Billing Fraud: Infusion therapy providers in South Florida will be required to reapply as Medicare providers as part of a two-year demonstration projecting targeting billing fraud, mostly among HIV/AIDS clinics in that state, the Centers for Medicare and Medicaid Services (CMS) announced recently. The demonstration is the third such project announced by CMS since July in which the government is attempting to curb fraud among durable medical equipment and home health providers in areas where fraud in these industries is especially high. In South Florida, Medicare infusion therapy scams have cost the federal government millions of dollars, CMS and the Department of Justice officials said.

Pathology Direct Billing: A California bill that would require direct billing for anatomic pathology services, not just cytopathology, recently passed the state legislature and is currently on the desk of Republican Gov. Arnold Schwarzenegger, who has 30 days to sign or veto the measure. If he does not act by then, the bill automatically becomes law. The bill would prohibit clinicians from billing patients and third-party payers for anatomic pathology services not performed or directly supervised by the clinician. Current state law prohibits direct billing for cytopathology, including Pap smears, and also bars physicians from marking up other clinical lab services.

Estimating Improper Payments: The federal government August 31 published a final rule setting out the obligations for states to provide information for purposes of estimating improper payments in the Medicaid program and State Children's Health Insurance Program. The rule, which takes effect October 1, follows up on comments submitted in response to an interim final rule from August 2006 on payment error rate measurement. It also describes the requirements for states to submit information to the CMS federal contractors for the purposes of conducting reviews of managed care and fee-for-service versions of government health programs.

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