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For Hospitals, Laboratories and Physician Practices

Anti-Markup Instructions Provide Clarification

Anti-markup rules that took effect July 1, 2009, will not apply to independent laboratories, and in many cases, the limitations will not apply to tests billed by pathologists or radiologists, according to new instructions issued by the Centers for Medicare and Medicaid Services (CMS).

In Transmittal 445, issued Feb. 13, 2009, CMS explains that the anti-markup limitation applies when a diagnostic service payable under the Medicare Physician Fee Schedule (MPFS) is performed by one physician or supplier and billed by another physician or supplier. The limitation applies when the physician performing the diagnostic test does not share a practice with the physician or supplier billing for the service.

The transmittal also summarizes the two alternatives under which the performing physician will be considered to share a practice with the billing physician or supplier. However, according to Robert Mazer, an attorney with Ober Kaler (Baltimore), the transmittal does not mention that the anti-markup limitations apply only when the diagnostic test is ordered by the billing physician or other supplier or by a party related to it through common ownership or control, as specified in Medicare-related party regulations.

A Medicare Learning Network (MLN) Matters article issued by CMS states that the limitation applies when a test is performed or supervised by a physician or supplier that does not share a practice with the physician or

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Stimulus Includes Whistleblower Protection Provision

The American Recovery and Reinvestment Act (Pub. L. No. 111-5) signed by President Obama on Feb. 17 includes a whistleblower protection provision that protects employees who reveal violations of the law related to stimulus funds.

Daniel P. Westman, with Morrison & Foerster LLP, McLean, Va., said in the law firm's Legal Update issued Feb. 20, "With little public notice, the Act adopted new whistleblower protections for employees of private employers and state and local governments who disclose waste, fraud, gross mismanagement, or a violation of law related to stimulus funds."

Given the overall intent of the act that

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supplier that *ordered* and billed for the test, but ignores the regulation provision also applying the limitation to tests ordered by a party "related to" the billing physician or supplier.

"Therefore, in most cases, the payment limitations will not apply to tests billed by radiologists or pathologists, even if the tests were performed by a physician who does not share a practice with the billing entity," says Mazer. "Medicare contractors may need to be reminded of this principle."

CMS also states that it will continue to apply a section of the *Medicare Claims Processing Manual* providing that the purchased diagnostic test limitations do not apply to independent laboratories. The policy reflected in the transmittal is consistent with the Medicare statute, which continues to apply anti-markup limitations to charges for diagnostic tests billed by a physician only, notes Mazer, but CMS had provided no previous indication that independent laboratories would not be subject to the new anti-markup limitations.

Medicare Payment

According to the transmittal, payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by or on behalf of the beneficiary) for the technical component (TC) or professional component (PC) of the diagnostic tests may not exceed the lowest of the following amounts:

- The performing supplier's net charge to the billing physician or supplier;
- The billing physician or other supplier's actual charge; or
- The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

The net charge must be determined without regard to any charge that reflects the cost of equipment or space leased to the performing supplier by the billing physician or other supplier.

Key Test

When the performing physician "shares a practice" with the billing physician or other supplier, the anti-markup provisions do not apply. There are two alternatives for determining whether the "sharing a practice" requirement is met:

—Alternative 1: Substantially All Services

The physician who supervises the TC of the test or performs the PC furnishes "substantially all" (at least 75 percent) of his or her professional services through the billing physician or other supplier.

—Alternative 2: Site of Service

Only TCs conducted and supervised and PCs performed in the "office of the billing physician or other supplier" by a physician owner, employee, or independent contractor of the billing physician or other supplier will avoid application of the anti-markup rules.

The "office of the billing physician or other supplier" is any medical office space, regardless of the number of locations, in which the ordering physician regularly furnishes patient care. This includes space where the billing physician or other supplier furnishes diagnostic testing, if it is located in the same building where the ordering physician regularly furnishes patient care.

If the billing physician or other supplier is a physician organization, the "office of the billing physician or other supplier" is a space in which the ordering physician provides substantially the full range of patient care services that he or she generally provides.

With respect to the TC, the performing supplier is the physician who supervised the TC; with respect to the PC, the performing supplier is the physician who performed the PC.

The anti-markup rules apply to services ordered by physicians, medical

groups, and other suppliers regardless of specialty, including pathologists and radiologists who may order diagnostic tests that were not specifically requested by the referring physician, legal analysts point out.

In the Feb. 13 transmittal, CMS also instructed contractors to inform providers about the correct format for billing services subject to anti-markup limits and when electronic and paper claims will be returned as "unprocessable."

Although the amended regulations that include the current anti-markup limitations became effective on Jan. 1, 2009, the transmittal's stated effective date is July 1, 2009. It's unclear whether the six-month gap will have any significance, says Mazer.

The transmittal is available online at www.cms.hhs.gov/transmittals.

EEOC Seeks Comments on Proposed GINA Rules

The Equal Employment Opportunity Commission on Feb. 25 released proposed regulations to implement the Genetic Information Nondiscrimination Act (GINA), which prohibits health insurers and employers from discriminating against someone on the basis of their genetic information.

The proposal was published in the March 2 *Federal Register*, beginning a 60-day public comment period. By law, EEOC must publish final rules under GINA by May 21, 2009, the one-year anniversary of the law's enactment. GINA's employment provisions, Title II, take effect Nov. 21, 2009.

In releasing the rules, EEOC assistant legal counsel Christopher Kuczynski said the commission has identified several areas it is particularly interested in receiving input on. EEOC's preamble to the proposed rule specifically invites comments on definitions unique to GINA, which include "family member," "family medical history," "genetic test," and "manifested or manifestation" as applied to a disease or disorder of a covered individual or family member.

The proposed rule states that a test to detect the presence of a virus that is not composed of DNA, RNA, chromosomes, proteins, or metabolites is not a "genetic test" under GINA and that drug and alcohol tests similarly are not covered, Kuczynski said. EEOC seeks comments on whether the final rule should include additional examples or what does or does not constitute a genetic test.

Exceptions

GINA provides six exceptions to the statutory sections prohibiting employers from acquiring genetic information. The proposed regulation addresses each of the exceptions, which are:

1. Where the employer inadvertently obtains genetic information;
2. Where the employer offers qualifying health or genetic services, including such services offered as part of a voluntary wellness program;
3. Where the employer requests family medical history to comply with the certification provisions of the Family and Medical Leave Act or state or local family and medical leave laws;
4. Where the employer acquires genetic information from documents that are commercially and publicly available, including print and Internet publications, except that an employer may not research medical databases or court records for the purpose of obtaining genetic information about an individual;
5. Where the employer acquires genetic information for use in the genetic monitoring of the biological effects of toxic substances in the workplace, pro-

vided that the employer complies with monitoring restrictions provided in the proposed regulations; and

6 Where an employer that conducts DNA analysis for law-enforcement purposes requires genetic information of its employees, apprentices, or trainees for quality control purposes to detect sample contamination.

In the proposed rule, the EEOC states that it is specifically seeking comments on subtleties of three of those exceptions: 1) what constitutes "voluntary" with respect to the employer-provided wellness program exception; 2) what should be included in the commercially and publicly available exception, particularly with respect to blogs and social networking sites; and 3) how the law enforcement exception should be applied.

The proposed regulation also reiterates the statutory prohibition against retaliation where an individual opposes any act made unlawful by GINA, files a charge of discrimination or assists another in doing so, or gives testimony in connection with a charge. The proposal also addresses treatment and disclosure of genetic information, medical information that is not genetic information, enforcement and remedies, and the relationship of GINA to other laws.

The proposed rule is available online at *www.eeoc.gov/policy/regs/index.html*.

SACGHS Issues Draft Report on Gene Patents

The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is requesting public comments on a draft report on gene patents and licensing practices and their impact on patient access to genetic tests.

The public consultation draft report is the result of work that began in 2004 when SACGHS identified the effect of gene patents and licensing practices on patient and clinical access to genetic tests as a high priority that warranted further study. In 2006, SACGHS formed a task force to guide its work in this area.

The task force commissioned case studies, compiled relevant information through a review of literature, and consulted with national and international experts and stakeholders.

The College of American Pathologists (CAP) has argued that exclusive or restrictive license agreements on gene-based tests have been used to prevent physicians and clinical labs from performing genetic tests as diagnostic procedures and that current practices in patenting and licensing of genetic sequences must be re-examined.

The task force reviewed a number of case studies to draw conclusions about how gene patents affect pricing, access to and availability of genetic tests, new innovation, and research related to genes. The case studies did not show "widespread overpricing" of genetic diagnostic tests that were patented and exclusively licensed relative to those that are unpatented or nonexclusively licensed.

So far, the panel found, patents covering genetic tests and related licensing practices do not appear to be impeding patient or clinical access to the tests. The group also found that patents may not serve as powerful incentives, but rather a minor stimulus, for either genetics research into the diagnostic arena or development of genetic tests.

SACGHS said that a set of principles and guidance documents should be developed that engage stakeholders over issues regarding patenting and licensing strategies for genetic diagnostic tests.

The *Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* is available at *http://oba.od.nih.gov/SACGHR/sacghs_public_comments.html*.

COMPLIANCE PERSPECTIVES

Marguerite Busch is the vice president/chief compliance officer for Pathology Associates Medical Laboratories (PAML) in Spokane, Wash.

Top Compliance Challenges for Laboratories

What are the priorities for a laboratory compliance officer in an increasingly challenging and competitive environment?

In the January 2009 issue of *G-2 Compliance Report* an article titled "Lab Compliance Officers Face Host of Challenges" focused on the results of a survey of lab compliance officers conducted by Washington G-2 Reports and Laboratory Management Support Services (LMSS) of Phoenix. Nearly half of the survey respondents were from hospital outreach labs and 22 percent from independent labs. As vice president and chief compliance officer for Pathology Associates Medical Laboratories (PAML) in Spokane, Wash., as well as for PAML's five joint ventures with hospitals, I have the unique responsibility of overseeing compliance for the two types of labs that comprise nearly 75 percent of those who responded. The effort to "do the right thing right" in any laboratory setting continues to be a challenge and these are some of the key issues I face. Some are very specific current issues, while others are continual and critical needs.

New/Revised ABN

When the Centers for Medicare and Medicaid Services (CMS) published the revisions to the Advance Beneficiary Notice (ABN; Form R-131) in March 2008, this set off a challenge to all labs that provide services to Medicare beneficiaries. Although the form itself appeared to look fairly similar to the former R-131-L, in fact, there were some significant changes that would impact lab employees obtaining the ABN, the lab's physician clients, and the Medicare beneficiaries themselves. Although the initial mandatory implementation date had been set for Sept. 1, 2008, CMS later extended that date to March 1, 2009, in response to a number of lab industry requests, and that extra time was definitely needed.

The major changes from the R-131-L and its requirements include:

- The requirement that a cost estimate be listed for each test on the ABN and be within 25 percent or $100 of the eventual cost charged to the patient;
- A third option for the Medicare beneficiary to choose from concerning their liability for payment;
- The requirement that the beneficiary not only sign but also insert the date on the ABN; and
- The prohibition from using the beneficiary's social security number or HCIN as the identifier on the ABN.

Among the challenges faced by labs, including PAML:

- Revision/reprinting of paper ABNs and subsequent retrieval of outdated forms prior to March 1;
- Reprogramming of electronic ABN programs that are the lab's product or working with laboratory information service (LIS) vendors to ensure their programming would be updated by March 1;
- Determining method for providing cost estimates in the field (i.e., in a pa-

tient service center or physician/client office) for each test; and

- Education of lab and physician office staff who may need to obtain an ABN, as well as the Medicare beneficiaries who would need to choose one of the three options for payment for their testing.

Now that the March 1 implementation date has passed, it will be important for all labs to monitor the success rate in obtaining valid ABNs so that additional training needs may be identified.

Physician Signature on Lab Orders

The requirement for documentation of the physician's intent to order a lab test has long been a challenge for laboratories as a lab typically relies on the properly completed requisition or an electronic order from the physician's electronic medical record (EMR) as its valid order. CMS, through the fiscal intermediary, carrier, or A/B Medicare administrative contractor, may require that this order also be documented in the patient's medical record along with the medical necessity for the order.

In the past year this was further complicated when a CMS transmittal was published that appeared to require that the physician's signature actually be on the requisition (a practice rarely in place at most labs). The subsequent publication of Transmittal 94 in August 2008 attempted to clarify this requirement by stating: "While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed," along with medical necessity documentation. So the challenge remains that even with the physician signature on the requisition, the lab's reimbursement may depend entirely on the physician's charting practices.

Contracts With Sources of Referral

A key component of successful clinical laboratory outreach programs is the building of relationships with physicians, clinics, hospitals, long-term care facilities, etc. (collectively "potential sources of referral"). These relationships may be simple and straightforward as serving as the reference laboratory by performing testing on samples sent into the lab from the ordering provider's office or facility or they may involve the leasing/subleasing of space for a patient service center, the provision of phlebotomy services in the provider's office, or the provision of connectivity to facilitate the ordering of lab tests and/or the delivery of lab reports between the provider's electronic medical record (EMR) and the LIS.

These relationships all must be evaluated under both the Anti-Kickback Statute and the Stark laws. These regulations and laws are ever changing and can be complex, so consulting with an attorney with expertise in this area may be prudent.

For instance, in October 2008, a clarification to the Stark Law was published that requires that all applicable agreements with sources of referral (either directly or indirectly) must be fully executed (i.e., signed by both parties) prior to the date upon which the space is occupied (if a patient service center lease or sublease) or the services are first provided (if an in-office phlebotomy arrangement).

Monitoring the Effectiveness of the Lab's Compliance Program

Since the Office of Inspector General's (OIG) Compliance Program Guidance for Clinical Laboratories was published in 1998, labs have known that a critical component of any compliance program is the auditing and monitoring of the effectiveness of the program. Whether this is done by the compliance officer/department, internal or external auditors, or department managers, the scope and details of the review/audit should be clear and well-defined and the reporting mechanism well-documented with appropriate action plans in place should any deficiency be found. As mentioned earlier, having a working relationship

with an attorney with expertise in health care law and in particular with laboratory issues is prudent. An effective compliance program involves regular review and audit of laboratory operations and may include:

- Completion rates for mandatory new employee, annual employee education/training in general compliance topics, as well as specific topics for identified "high-risk" departments;
- "Order to Report to Claim" audits, which would include not only confirming that the tests that were ordered were those that were performed and those for which a claim was filed, but also whether the ICD-9 code/diagnosis narrative on the requisition was the same as on the claim, whether an ABN was needed and a valid ABN executed, whether a Medicare Secondary Payer questionnaire was completed, etc.; and
- Verification that new/revised/deleted CPT codes are reflected in the current chargemaster as of January 1 of each year and also that any changes in methodology during the year have resulted in updates to the chargemaster if needed.

Other review/audit subjects that should be considered:

- Referred test review to determine whether the laboratory falls within the provisions of the "70/30 rule" by referring less than 30 percent of testing to other laboratories so that the lab can bill Medicare directly;
- Test utilization review that compares the 30 most frequently billed tests for the year to the previous year's volume of those tests and the probable cause for any increase greater than 10 percent;
- Review of contracts with sources of referral (e.g., patient service center leases, phlebotomy services) for appropriate execution of the contract, compliance with the terms of the contract, verification of fair market value (if applicable), etc.;
- If applicable, review of standing orders related to documentation of specific patient/specific test(s)/specific time interval, as well as annual (at a minimum) review/renewal by the ordering provider; and
- If applicable, review of billing for end-stage renal disease (ESRD) patient testing or long-term care/skilled nursing facility patient testing for compliance with the unique and specific billing rules for these patient types.

Keeping Current With Compliance Changes and Challenges

Lastly, there is an ongoing need to have resources available for timely and accurate information regarding changes that have been made or may be contemplated by CMS, the OIG, local fiscal intermediary, carrier or A/B Medicare administrative contractor (MAC), or other agencies with jurisdiction over laboratory practices. There are a number of excellent sources for this information:

- Listservs available through CMS and OIG that are free and send regular notifications via e-mail on a variety of subjects: (www.cms.hhs.gov/AboutWebsite/EmailUpdates/list.asp) or (http://oig.hhs.gov/mailinglist.asp);
- Review of the annual OIG Work Plan, which is typically published in the fall of each year and gives insight into various projects to be addressed by the OIG the following fiscal year, including those that may involve laboratories;
- Laboratory-specific newsletters/publications such as *G-2 Compliance Report* and *National Intelligence Report*;
- Laboratory industry conferences (in-person or via video/audio conference), which provide sessions devoted specifically to compliance issues including those sponsored by IOMA, the Dark Report, American Association for Clinical Chemistry (AACC), American Society for Clinical Laboratory Science (ASCLS), the Clinical Laboratory Management Association (CLMA), and others; and

- ❖ Networking with peer laboratories to share best practices, helpful tips, and tools for conducting relevant reviews and audits, as well as education and training materials.

One Final 'Need'

Many laboratories have a person serving as compliance officer or compliance coordinator who moved into that role at the inception of that lab's compliance program (perhaps as far back as 1998 when the OIG compliance guidance document was published). In those situations, the person has had the advantage of learning about laboratory compliance from its beginning as a formal program and then growing in their knowledge and expertise as laboratory compliance requirements became more well-defined and more resources for training became available. The "need" now is for more laboratory professionals to be positioned through training and experience to acquire that same level of expertise so as to continue to grow and expand the compliance programs for a new generation of laboratorians and to prepare them to face any new challenges posed by compliance regulations.

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Improper Coding May Have Led Hospitals to Overbill Medicare $25 Million, OIG Says

Hospitals may have improperly coded more than 15,000 claims during a three-year period ending in 2005, causing Medicare to overpay the hospitals by an estimated $25 million, according to a Department of Health and Human Services Office of Inspector General (OIG) audit report posted March 10.

The report, *Hospital Compliance with Medicare's Postacute Care Transfer Policy During Fiscal Years 2003 Through 2005*, found that 92 claims in a 150-claim sample were improperly coded as discharges to home rather than transfers to post-acute care.

Most of the overpayments identified in the report occurred because the Centers for Medicare & Medicaid Services lacked adequate payment system controls, according to the report.

Based on the sample results, OIG estimated that hospitals nationwide may have improperly coded 15,051 claims and that Medicare overpaid $24.8 million to these hospitals for the three-year period ending Sept. 30, 2005, according to the report.

Medicare's post-acute care transfer policy distinguishes between discharges and transfers of beneficiaries from hospitals under the inpatient prospective payment system.

Under the policy, Medicare pays full diagnosis-related group (DRG) payments to hospitals that discharge inpatients to their homes. In contrast, for specified DRGs, Medicare pays hospitals that transfer inpatients to certain post-acute care settings, such as a skilled nursing facility or home health care, a per diem rate for each day of the stay, not to exceed the full DRG payment for a discharge.

Most of the overpayments identified in the report occurred because the Centers for Medicare & Medicaid Services lacked adequate payment system controls, according to the report.

The report recommends that CMS instruct Medicare fiscal intermediaries or Medicare administrative contractors to recover $137,226 in overpayments identified in the OIG's sample and review the remaining claims in the sample to identify and recover the additional estimated overpayments of nearly $25 million. CMS concurred with the report's recommendations, stating that it would seek to recover the overpayments.

Whistleblower Protection Provision, *from page 1*

stimulus funds should not be wasted, employers should assume that the whistleblower provisions apply to anyone who receives a contract, grant, or other payment appropriated or made available by the stimulus bill, Westman said.

The language in the whistleblower provision was intentionally made so broad that it protects whistleblowers uncovering fraud in Medicare and Medicaid and other programs that receive stimulus funds.

The whistleblower provisions in the $787 billion economic stimulus package, which includes additional Medicaid funding for states, federal funding to help spread the adoption of health information technology, and money to help workers who have lost their jobs retain their health insurance, excludes the federal government and its agencies. However, it does extend the protections to employees of federal, state, and local government contractors and subcontractors, Westman said.

Broad Language

Taxpayers Against Fraud President Joseph E.B. White says that although the legislation only applies to anyone receiving the stimulus funds, the language in the whistleblower provision was intentionally made so broad that it protects whistleblowers uncovering fraud in Medicare and Medicaid and other programs that receive stimulus funds.

Westman said that because the act involves the provision of public funds to employers in both the government and private sectors, the legislation melds together the categories of protected complaints typically found in whistleblower laws applicable to both the government and private sectors.

Accordingly, the act greatly expands the subject matters of protected complaints in private sector employment to include the categories of mismanagement, waste, and abuse with respect to stimulus funds, he added.

The whistleblower protection provision states that any nonfederal employer who receives funds under the act may not fire, demote, or otherwise discriminate against an employee who reveals information on mismanagement, waste, dangers to public health and safety, or violations of law related to the grant or contract. The bill would require an inspector general to investigate all claims of reprisal unless they are determined, within 180 days, to be frivolous.

It also requires, not later than 30 days after receiving an Office of Inspector General report, the head of the agency to determine if the nonfederal employer has been engaged in a prohibited reprisal and order the employer to take action to address the issue, reinstate the person, and pay the complainant an amount equal to all costs and expenses incurred in bringing the complaint. If an agency head denies relief or does not take action within 210 days, the complainant can seek compensatory damages in court.

Statute of Limitations

However, what is missing from the provision is a statute of limitations on reprisal claims, Westman says, noting that the issue may be addressed when regulations are issued.

The stimulus package includes best practices anti-retaliation rights for any workers involved with the new federal spending. That includes contractors, grantees, and state and local government employees who work in programs that receive stimulus funding.

The Government Accountability Project (GAP), a whistleblower protection organization in Washington, said in a press release that it was frustrated by the failure to extend whistleblower rights to federal government workers, "who are best positioned to keep the spending honest."

"It is not too late for accountability," GAP Legal Director Thomas Devine said. "After nearly 10 years of hearings and votes, there is no excuse to spend nearly a trillion dollars without safe passage for federal employees who risk their careers to keep it honest. Congress has more than enough time, though, to finish locking in best practice rights for federal whistleblowers before the money starts getting spent in 120 days."

First Funds Dispersed

Announcing the first dispersal of the economic stimulus package, President Obama said $15 billion would be dispersed Feb. 25 for Medicaid relief to help low-income families pay for health care. Obama also announced that Vice President Joe Biden will oversee the administration's implementation of the stimulus legislation.

In addition, he named Earl Devaney, inspector general at the Department of the Interior—whose background is in law enforcement—to be the White House watchdog over stimulus spending, in an effort to demonstrate accountability and transparency.

Obama addressed the nation's governors at their winter conference Feb. 23 by discussing how to implement the $787 billion economic stimulus package passed by Congress.

Health Care Task Force

Meanwhile, the National Governors Association (NGA) has named a task force for health care reform. "Governors understand the vital role that health plays in competitiveness and quality of life and have made providing efficient, cost-effective health care to their citizens a top priority," NGA said in a press statement.

NGA added, "The Task Force is designed to identify and define gubernatorial priorities and to inform and advise the work of Congress and the Administration."

The task force includes Vermont Gov. Jim Douglas (R) and Michigan Gov. Jennifer M. Granholm (D) as co-chairs, Pennsylvania Gov. Edward G. Rendell (D), Connecticut Gov. M. Jodi Rell (R), Georgia Gov. Sonny Perdue (R), Kansas Gov. Kathleen Sebelius (D), Massachusetts Gov. Deval Patrick (D), Minnesota Gov. Tim Pawlenty (R), North Dakota Gov. John Hoeven (R), Tennessee Gov. Phil Bredesen (D), Utah Gov. Jon Huntsman Jr. (R), and Washington Gov. Christine O. Gregoire (D).

Proposed Budget Includes More Funding for Anti-Fraud Efforts

President Obama's fiscal year 2010 proposed budget includes several proposals to reduce health care fraud, waste, and abuse that could save the government about $5 billion over 10 years, according to budget documents the White House released Feb. 26.

The most substantial estimated savings would come from increasing program integrity activities at the Department of Health and Human Services (HHS). Increased investment in fiscal years 2010 through 2014 would result in $2.7 billion in savings at HHS, according to the budget outline. The budget summary was released Feb. 26; the full budget will be released in April.

The budget includes a $311 million increase in funding for the Health Care Fraud and Abuse Control Program (HCFAC), which is administered by the HHS secretary and the attorney general. The increase would bring the total funding commitment by the administration for HCFAC to almost $1.5 billion.

Other cost-saving proposals outlined in the budget include using radiology benefit managers for Medicare imaging payments, using the National Correct

Coding Initiative edits for Medicaid payments, and providing private sector enhancements to ensure Medicare pays accurately. The private sector enhancement proposal would save the Medicare program $2 billion over 10 years, according to the budget, but no explanation of what those enhancements would be was included. Several lawyers working in the field said that it might have to do with recovery audit contractors.

The budget also includes a proposal to address financial conflicts of interest in physician-owned specialty hospitals but does not include an estimate for how much this would cost or save.

HCFAC Program

The HCFAC program was established by Congress in the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) to fight fraud and abuse in federal health programs. The HCFAC account is apportioned to the HHS Office of Inspector General, Department of Justice, and other agencies through an annual negotiation process.

The increased funding for fraud enforcement outlined in the budget will have a greater impact than the other proposals intended to shut down certain areas where fraud is taking place, Louis Saccoccio, executive director of the National Health Care Anti-Fraud Association, said.

"When there is fraud, the folks that commit the fraud move from one thing to the next," Saccoccio said. That is why it is important to fund anti-fraud efforts "to a level where you have the resources both on the investigative side and the prosecutorial side to really make a dent."

The HCFAC program recovered $1.8 billion for federal health programs in fiscal year 2007, according to an annual report released in December 2008 by the HHS and DOJ. The program has resulted in more than $11 billion in recoveries for federal health programs since its inception in 1997, the report said.

Correct Coding Initiative

If the National Correct Coding Initiative (CCI) edits were used to ensure that Medicaid payments are appropriate, the government could save $620 million over 10 years, according to the budget. Legislation was introduced in the House and the Senate during the 110th Congress to implement mandatory state use of the National Correct Coding Initiative, but did not move.

CCI is a system of automated edits currently used to evaluate Medicare claims. Although CCI edits are mandatory in the Medicare program, state Medicaid agencies are not required to use them to process their claims. According to the most recent GAO report on the issue from 2004, only seven states use all or some of the coding edits. GAO recommended that CMS encourage states to explore the use of edits.

Specialty Hospitals

The budget included a proposal to address the financial conflicts of interest in physician-owned specialty hospitals, but did not include an estimate of cost or potential savings.

The proposal is similar to a provision that was removed from legislation to reauthorize the State Children's Health Insurance Program before Congress passed the bill at the beginning of February.

The provision would have closed what supporters called a loophole in the physician self-referral law (known as the Stark law) that allows doctors to refer Medicare patients to hospitals in which they have ownership interests.

The specialty hospital funding provision, which would have banned new physician-owned hospitals, was aimed at curbing physician ownership in single-specialty hospitals, such as heart hospitals, that critics have said allow doctors to profit unfairly from referring patients to their own facilities and driving up health care costs.

RAC Modifications: While the Centers for Medicare and Medicaid Services (CMS) rolls out a national program for recovering payments from claims errors, the hospital industry will be pushing for changes in the system, according to an official with the American Hospital Association (AHA). President Obama's fiscal 2010 budget proposal, unveiled in February, discusses strengthening program integrity in the context of minimizing inappropriate Medicare payments, said Don May, vice president for policy at the AHA. CMS recently announced some changes to the RAC program, including reducing from four to three years the RAC "look-back" period. AHA will try to get that period limited to one year, May said. AHA also will ask CMS to limit the number of medical record requests that RACs can make for inpatient hospital claims to a maximum of 50 records per NPI per month.

FCA Bill Increases Liability: A bill introduced in the Senate Feb. 5 aimed at improving enforcement against mortgage, securities, and other fraud also includes changes to the False Claims Act (FCA) that would increase the liability for contractors and subcontractors who submit false claims for repayment on government contracts. The provision in the Fraud Enforcement and Recovery Act of 2009 (S. 386) ensures the original intent the FCA adheres to and prevents wrongdoers from evading liability simply by hiring subcontractors, said Sen. Charles Grassley (R-Iowa), one of the bills sponsors.

Massachusetts Adopts Rules on Gifts: Massachusetts health officials on March 11 approved final regulations requiring pharmaceutical and medical device manufacturers to meet codes of conduct regulating payments to health providers by this July and to begin disclosing gifts to providers by July 2010. The Public Health Council voted unanimously to adopt a set of rules for implementing a law enacted last summer that limits payments to health providers and requires disclosure of gifts with a value of at least $50. The regulations adopted by the panel were revised from an original version issued last December to address various objections by consumer and advocacy groups.

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