G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

New Draft Compliance Guidance Targets Drug Companies' Financials Favors To Docs

Drug companies that offer entertainment, discounts on products, "educational" grants and upfront rebates to physicians could be in violation of the federal anti-kickback law, warns new draft compliance guidance for the pharmaceutical industry, released Sept. 30 by the HHS Office of Inspector General.

The guidance, designed to limit the influence that drug makers exert over physicians and other healthcare providers, should help create checks and balances for the pharmaceutical industry, IG Janet Rehnquist told health lawyers on Oct. 1.

"The industry is ripe for [such] guidance," Rehnquist said, citing recent fraud settlements by drug companies, including the $875 million settlement by TAP Pharmaceutical Products in October 2001. Rehnquist spoke at the Fraud and Compliance Forum, held in Washington, DC, by the American Health Lawyers Association and the Health Care Compliance Association.

The draft guidance details how to

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Inside this issue

Be Wary When Giving, Receiving Gifts *Set Clear Boundaries On What's Acceptable*

With the holidays fast approaching, now is a good time for your compliance program to remind employees of your policies on the giving and receiving of gifts.

Underscoring the importance of such education is the latest special advisory bulletin from the HHS Office of Inspector General. It offers "bright-line guidance" on gifts from healthcare providers to Medicare and Medicaid beneficiaries. Other kinds of gift-giving—in particular to referral sources, for example, from a laboratory to a physician office or from hospital management to physicians—typically are restricted by the federal anti-kickback statute or the Stark self-referral law.

In the private sector, ethical guidelines on gifts to physicians have been formulated by both the American Medical Association and the Pharmaceutical Research & Manufacturers of America (*see p. 10*).

"Providers need to be aware of what they're allowed to do when it comes to gifts," says attorney **Julie Kass** with Ober/Kaler (Baltimore, MD). "The government believes it has issued guidance on this in its special fraud alerts."

Gifts To Beneficiaries

The OIG's latest advisory warns that gifts or other inducements to choose a particular provider are illegal remuneration under the 1996

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DOT Toughens Standards For Transporting Infectious Substances
Exemptions Granted For Blood Products, Some Diagnostic Specimens

Federal requirements governing transport of infectious substances, including regulated medical waste, became tougher this Oct. 1, under a final rule published by the U.S. Department of Transportation.

The rule, developed by DOT's Research & Special Programs Administration (RSPA), extends the Department's hazardous materials regulations to biological products, diagnostic specimens and infectious substances.

But it grants an exemption to diagnostic specimens transported in dedicated motor vehicles by private or contract carriers.

It also exempts FDA-licensed blood, blood products and blood transported for the production of blood products (including test samples) from most of its provisions. Blood collection facilities already are subject to OSHA regulations. Specifically, the final rule:

- Revises current packaging requirements for infectious substances to make them consistent with international performance standards.
- Limits the current biological products exception to those biological products subject to federal licensing or permit requirements.
- Sets new bulk packaging standards for transporting regulated medical waste.

WHO Criteria

New classification criteria for infectious substances are based on definitions by the World Health Organization, consistent with United Nations recommended standards. WHO risk groups for infectious substances are ranked according to the degree to which they cause injury through disease, with risk group 1 presenting the lowest risk.

Under the final DOT rule, substances that fall under WHO infectious substance risk groups 2, 3 and 4 must be transported in specification triple-packaging and be marked, labeled and accompanied by appropriate shipping and emergency response documentation. Risk group 1 materials are not subject to the rule.

Diagnostic specimens must be triple-packed (a primary receptacle, secondary packaging and an outer packaging) and must be capable of successfully passing a drop test from 1.2 meters (3.9 feet). The outer packaging must be labeled "diagnostic specimen" to communicate a potential hazard to transportation workers.

Limits For Air Shipment

The final rule also raises the maximum volume for shipment of body fluids by air to 1,000 mL for primary receptacles in outer packaging not to exceed 4L.

Resource

- DOT final rule: transport of infectious substances, online at *http://hazmat.dot.gov/67fr-53118.pdf*

■ **Draft Guidance,** *from p. 1*

avoid kickback and False Claims Act liability in dealing with physicians and other providers. It also points the industry to its own voluntary code, developed by the Pharmaceutical Research & Manufacturers of America, as a model for conduct. Together, the guidance and the voluntary code are designed to stop drug companies from offering financial incentives to prescribe or recommend certain drugs or to switch patients from one medicine to another.

Among specific risk areas cited in the draft guidance:

- *Integrity of data used to establish government reimbursement*. Drug companies may be subject to civil and criminal penalties if they report inaccurate or incomplete data on the prices or sales of their products.
- *Kickbacks and other illegal remuneration*. Activities that fit within a safe harbor are immune from sanction under the anti-kickback statute. Other activities designed to influence physicians will be suspect.
- *Discounts and other terms of sale*. Price concessions, discounts and any remuneration provided as part of a sale, unless specifically covered by the discount exception, potentially implicate the anti-kickback statute.
- *Average wholesale price*. Drug companies that manipulate the AWP to increase customers' profit would be in violation of the statute.
- *Relationships with physicians and other healthcare professionals*. Drug companies should ensure that they compensate healthcare professionals only for providing actual, reasonable and necessary services and that the arrangements are not merely token arrangements created to disguise otherwise improper payments.
- *Relationships with sales agents*. Companies will be held responsible not only for their own employees, but also for sales agents and contractors who engage in improper marketing and promotional activities on their behalf.
- *Drug samples*. Pharmaceutical manufacturers must ensure that drug samples provided free to physicians are not sold to patients or billed to federal healthcare programs.

Comments on the draft are due 60 days after its publication in the *Federal Register* (expected Oct. 3). The draft is online at *http://oig.hhs.gov/fraud/docs/complianceguidance/draftcpgpharm09272002.pdf*.

Do You Have An Employee Grievance Process That Works?

Avoiding Lawsuits, Boosting Worker Morale Are Chief Benefits

In an era when whistleblower cases against healthcare providers are on the rise and many result in settlements that cost companies multi-millions of dollars, an effective employee grievance system can be a critical tool to help employers ward off such lawsuits.

The federal False Claims Act Amendments of 1986 created strong financial incentives for individuals to sue providers on behalf of the government for alleged submission of false claims to federal healthcare programs. A successful *qui tam* plaintiff—or whistleblower—is entitled to up to 30% of the money the government recovers, plus attorney fees. Since the amendments were passed, the number of *qui tam* suits filed has increased steadily, from 33 in 1987 to 483 in 1999 (the most recent year for which figures are available). Recoveries have skyrocketed to more than $3 billion in 2000 from $355,000 in 1988, according to the U.S. Department of Justice.

Donald Phin

One way to reduce the risk that a baseless *qui tam* suit will be brought against you, say experts, is to ensure that employees are treated fairly and that you have an effective process to address worker grievances when they occur.

"Having a good system for addressing complaints is the best way to protect yourself from whistleblower suits," says attorney Ronald Clark with Arent Fox (Washington, DC). "In my experience, many cases brought by relators [whistleblowers] stem from the fact that they had a complaint about something and nobody listened to them."

While the grievance process will vary from one provider to another, employers should keep in mind some general "do's and don'ts" when developing or refining an internal complaint system, advises Donald Phin, president of Employer Advisors Network Inc., a human resource consulting company based in Reno, NV.

Do

❖ Do survey employees twice a year about any concerns they have (*see model survey*). This will help you spot complaints early, so they can be addressed before becoming major problems for your organization. "This allows you to take a front-end approach to employee satisfaction," says Phin. "Instead of waiting for employees to come to you with a problem, go to them first. Not only

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Sample Employee Compliance Survey

We are committed to eliminating wrongful and unsafe conduct. It is never in a company's best interest to have its managers or employees violate any laws, policies, safety or ethical standards. When properly used, this survey will allow our company to maintain trust and avoid unnecessary claims. If you have any comments regarding the use or improvement of this survey, we would like to know about them. Thank you.

Please help us by the answering the following questions:

1 Do you understand the company policies that prohibit and require you to report harassment, discrimination, safety and ethical violations?

❑ Yes ❑ No

2 Are you aware of, have you witnessed, or have you been a victim of, the violation of any company policy, including those prohibiting harassment, discrimination, safety or ethical violations?

❑ Yes ❑ No

3 Have you reported any and all workplace injuries by completing an Injury Report?

❑ Yes ❑ No

4 Is there any other personnel, compliance or safety issue you feel needs to be addressed?

❑ Yes ❑ No

Name _____

Date _____

Signature _____

Please return this form to _____within two working days.

Source: Employer Advisors Network Inc.

■ **Grievance Process,** *from p. 3*

will it encourage them to speak up about concerns, but it also may make the harasser or wrongdoer think twice about what they're doing."

❖ Do put the grievance policy in writing and include it in the employee handbook. All employees should be required to read the handbook and sign an acknowledgment that they have read and understood it. Also, discuss the policy during employee training.

> ***"Having a good system for addressing complaints is the best way to protect yourself from whistleblower suits"***
> ***Ronald Clark***
> ***Arent Fox***

❖ Do list the established reporting hierarchy. For example, employees should be instructed to go to their direct supervisor first. If they don't receive a written response within a reasonable period of time, they should then go to the organization's human resource department.

❖ Do promise to investigate and respond to a complaint in a "prompt and thorough manner." An investigation should begin immediately after a complaint is received, though the amount of time spent on the investigation will vary depending on the complaint. "It's a weighing act. Employers must use their best judgment to determine what's reasonable," Phin says.

❖ Do require that complaints be filed in written form and document each step of the investigation process. Written documentation will be important if you ever have to defend yourself in court.

❖ Do ensure that the culture of your organization supports the grievance policy. "A policy is no good if employees know that management doesn't take it seriously," Phin points out. "The commitment has to come from the top."

Don't

❖ Don't assume that employees will always come to you with their concerns when they first have them. Sometimes they need to be encouraged to speak up if they are experiencing problems in the workplace.

❖ Don't promise to investigate and respond to a complaint within a specified period of time. Committing to a deadline that you might not be able to meet can cause additional problems if you miss it.

❖ Don't promise confidentiality. You might not be able to uphold that commitment as you conduct your investigation.

Resources

❖ Ronald Clark: 202-857-8911

❖ Donald Phin: 619-204-7446

CMS Steps Up Scrutiny Of Provider Billing Numbers

Numbers Deactivated After Four Quarters Of Inactivity

Physicians and other healthcare providers who don't bill Medicare for four consecutive quarters will have their billing number deactivated, warns the Centers for Medicare & Medicaid Services.

And that means no reimbursement for any claims using that number.

In a recent transmittal to local Medicare contractors, the agency says providers may reactivate a billing number, but to do so, must submit a new CMS 855 form or update an existing one.

The crackdown, in part, is designed to prevent fraud and abuse schemes by individuals who use billing numbers assigned to providers who are no longer practicing or who are dead.

Providers also could have their billing number deactivated if they don't notify their intermediary or carrier of a change to information on their Medicare enrollment form within 30 days of the change. Notification must be submitted on the CMS 855. In most cases, providers will have to fill out only those portions pertinent to the change.

However, any change to the pay-to-address and any group that's adding a new individual and wants to have benefits reassigned from that individual must submit CMS 855 in its entirety.

Provider Enrollment Changes

The CMS transmittal contains a number of other refinements to the Medicare provider enrollment process, which many in the healthcare industry have criticized as overly burdensome. Physicians, for example, have complained that enrollment forms are too time-consuming.

While CMS has attempted to streamline the process, including issuing more user-friendly forms in November 2001, physician groups contend that the process still needs improvement.

The American Medical Association has urged CMS to issue temporary provider numbers that would allow physicians to see Medicare patients while their enrollment forms are being processed. AMA also has called for forms that can be completed on the Web, with relevant attachments forwarded to the carrier as needed.

Resource

❖ CMS Transmittal 29, online at *http://cms.hhs.gov/manuals/pm_trans/R29PIM.pdf.*

COMPLIANCE PERSPECTIVES

Using The New ABNs: How To Navigate Regulatory Pitfalls & Minimize Risks

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Effective Oct. 1, 2002, the Centers for Medicare & Medicaid Services (CMS) has announced, the newly approved Advance Beneficiary Notice (ABN) forms must be used by physicians, practitioners, other providers and suppliers in connection with claims submitted for reimbursement under Part B. Accompanying the announcement were 40 pages of instructions on ABN use. This article discusses the risks and some of the more challenging areas that providers and suppliers face in executing a proper ABN, and presents strategies to deal with these risks and challenges. The new forms and provisions have critical implications for clinical laboratories, as discussed below.

1. Why Use An ABN?

An ABN is a written notice given to a Medicare beneficiary, before a service or item is furnished, notifying him/her that Medicare is likely to deny payment for that specific service or item, and the reason why. ABNs are required for use with Medicare beneficiaries only.

The ABN informs the beneficiary that he/she will be personally and fully responsible for payment if (as expected) Medicare denies payment. It lets the beneficiary make an informed decision whether to receive the service, knowing that he/she may have to pay for it out-of-pocket. It also protects the provider or supplier, since the beneficiary may be held liable for payment if given a proper ABN prior to provision of the service.

Claims may be submitted, even though a payment denial is expected, for various reasons:

- If a beneficiary (or derivatively a supplier) wishes to contest CMS' (or its contractors') view that a service is medically unnecessary, a denial must first be obtained to trigger appeal rights.
- Some secondary insurance policies require a Medicare denial before a claim can be paid under the policy.
- Beneficiaries have the option of demanding that claims be submitted even for non-covered services.

In each of these circumstances, Medicare is not expected to pay and the ABN puts the beneficiary on notice that he or she may be the financially responsible party.

2. An ABN Must Be Specific

The ABN must identify the specific item or service for which denial is expected and clearly state why Medicare denial is expected. It is not enough to simply state "medically unnecessary." You may customize the reason for expected denial (the "because" box) to list the reason(s) that you frequently find applicable (*e.g.*, Medicare does not pay for this item or service for your condition). Listing multiple reasons that apply under different circumstances, however, without indicating which applies in the beneficiary's particular case may render the ABN defective.

Medicare's New ABNs: *Key Facts*

- Two standardized formats, each a single page; use is mandatory, as of Oct. 1, 2002:
  (1) CMS-R-131-G: "general use" ABN
  (2) CMS-R-131-L: ABN for use with laboratory tests, including physician-ordered tests. Labs may also use the general-use format.
- Labs may reproduce the ABN on the reverse of their requisitions.
- Use of old or modified ABNs may not be effective to protect you from financial liability.
- The new ABN forms can be downloaded from *http://cms.hhs.gov/medicare/bni*. The ABN instructions (Transmittal AB-02-114, July 31, 2002) are online at *http://cms.hhs.gov/manuals/memos*.

3. Options & Related Modifiers

The ABN spells out the options available with respect to the provision of an item or service. The beneficiary may choose:

- ❖ Option 1 (Yes), in which case he/she chooses to receive it and to be responsible for payment if Medicare does not pay, or
- ❖ Option 2 (No), in which case he/she chooses not to receive it.

If the beneficiary selects Option 1 and receives the item or service, you must submit a claim to Medicare and *must* use modifier "GA" on line 24D of the CMS-1500 claim form. This modifier indicates that you expect Medicare to deny the claim as not reasonable or necessary, and you have on file a signed ABN. The ABN is *not* submitted with the claim; however, you should keep the original ABN in the event of a future dispute or appeal.

If an ABN was not obtained and the beneficiary nevertheless received the item or service, you may use modifier "GZ" on the CMS-1500 to indicate that you expect a denial from Medicare, and you did not obtain an ABN. Use of this modifier is not mandatory.

4. Risk Areas

Failure to comply with Medicare rules on the use and execution of an ABN can expose you to numerous risks, including financial liability—and even allegations of fraud and abuse or violation of other Medicare provisions. As a result, you should be aware of the following risk areas in implementing the new ABNs.

- ❖ *Avoid routine use of ABNs, generic ABNs and blanket ABNs.*

"Routine" use means providing an ABN where there is no specific reason to expect a Medicare payment denial. "Generic" ABNs simply indicate Medicare denial is possible or you never know whether Medicare will pay. "Blanket" ABNs are given for all items or services.

ABNs should only be used when you have a reasonable expectation that Medicare will deny payment for a specific item or service, either on the basis of non-coverage for lack of medical necessity or on one of the statutory bases that trigger requirements for an ABN (*e.g.,* custodial care, a hospice patient determined not to be terminally ill, a home health patient who is not homebound or requiring intermittent skilled nursing care).

There are several exceptions to the general prohibition on routine ABNs. CMS explains that they may be routinely given to beneficiaries and be considered valid in the following situations:

- — Services which are always denied for lack of medical necessity (*e.g.,* where a Medicare national coverage decision states that an item or service is never covered);
- — Experimental items and services (*e.g.,* laboratory tests for "research use only" or for "investigational use only");
- — Certain frequency-limited items and services; or
- — Medical equipment and supplies denied because the supplier had no supplier number or made an unsolicited telephone contact.

- ❖ *Avoid use of signed blank ABNs.*

You may not obtain a beneficiary's signature on a blank ABN, then later complete the ABN. Such an ABN is invalid and will not protect you from liability.

- ❖ *Obtain a new ABN to cover an extended course of treatment after one year, and when a beneficiary's course of treatment changes.*

You may use a single ABN to cover an extended course of treatment, provided it lists all the items and services for which you expect Medicare not to pay. For example, "standing order" lab tests would be considered an extended course of treatment, and a single ABN would suffice. A single ABN for an extended course of treatment is valid for one year. After one year, you must execute a new one to cover the remainder of the course of treatment. You also must execute a new ABN if, during the extended course of treatment, additional items or services are to be furnished to the beneficiary and you expect Medicare won't pay for them.

- ❖ *Don't rely solely on a telephone notice.*

As a general rule, you should hand-deliver the ABN to the beneficiary (or authorized representative). Retain the original and give a copy to the beneficiary immediately after he or she signs it.

Telephone notice may be effective, provided you immediately follow-up the phone contact with a written mailed ABN or a personal visit at which the beneficiary signs the ABN. Under these conditions, Medicare will accept the time of the telephone notice as the time of the delivery of the ABN.

- ❖ *Don't deliver an ABN to a beneficiary who cannot comprehend it.*

Use Of The "GA" Modifier

Always use the "GA" modifier if you gave the beneficiary an ABN.

You must use this modifier on line 24D of the CMS-1500 to indicate that you expect Medicare to deny the claim as not reasonable and necessary, and you have a signed ABN on file. *If you fail to use this modifier and the claim is denied, the beneficiary will not be held liable—you will.* Your only remedy is through the appeals process.

Medicare further cautions that failure to use the "GA" modifier when an ABN was obtained may give rise to fraud and abuse implications for abusive billing patterns.

An ABN is not properly delivered unless the beneficiary can understand its contents. If the beneficiary is comatose, confused, legally incompetent or under great duress, use of an authorized representative is required. An authorized representative, interpreter or other measures must be used if the beneficiary is not literate in the language of the ABN or is visually impaired.

Give the beneficiary (or authorized representative) an opportunity to ask questions about the ABN. Failure to respond accurately and thoroughly to inquiries may constitute a defective notice.

❖ *Avoid last-minute delivery of the ABN.*

Under Medicare's "timely delivery" rule, the ABN must be given to the beneficiary far enough in advance of the provision of medical items or services to avoid coercion and allow him/her to make an informed decision about receiving or not receiving the items or services.

CMS recognizes that unforeseeable situations may occur and adopts a common-sense approach. For example, if a physician discovers an unexpected condition while examining the beneficiary, and that condition requires further immediate study, the "timely delivery" rule would not preclude the physician from giving the beneficiary an ABN in the exam room.

CMS further explains that in instances where a physician orders a lab test and sends the sample to a lab without obtaining an ABN, the lab may contact the patient and give him or her an ABN, prior to testing the sample, without violating the "timely delivery" rule. This option protects the lab in case Medicare denies payment.

5. Intricacies In ABN Use

❖ *Emergency Settings*

Under the Emergency Medical Treatment & Labor Act (EMTALA), medical personnel may not inquire about insurance coverage or a patient's ability to pay before the patient is screened and stabilized in any setting where EMTALA applies. This poses an apparent conflict with Medicare's ABN rules, which require that a beneficiary sign an ABN before receiving services that Medicare may not reimburse.

In a Nov. 10, 1999 advisory bulletin, CMS (then HCFA) and the HHS Office of Inspector General advised hospitals not to give ABNs to emergency room patients before they are stabilized. Even if a patient does not appear to have a life-threatening condition, the hospital should not give the patient an ABN until it has satisfied its obligations under EMTALA. The rationale is that a patient in a medical emergency, or otherwise under great duress, may be limited in his or her ability to make a rational, informed decision.

CMS contends that the ABN requirements are not incompatible with EMTALA, because EMTALA does not prohibit asking payment questions entirely—it just precludes them before the patient is screened and stabilized. Once that occurs, EMTALA no longer applies and the patient may be given an ABN, if appropriate.

❖ *Cost Estimates*

The ABN forms include a field for the estimated cost of the item or service. This is not a required field. But CMS strongly urges you to give a cost estimate to enable beneficiaries to make an informed decision about whether they want to receive the item or service. If a fee schedule is not available, you should estimate the cost to the best of your ability and respond as you would if a private-pay patient asked about cost.

Some patients may decline a service if the provider is unable to give a reasonable estimate of its cost. An ABN lacking an estimated cost, or containing an estimated cost that deviates from the actual cost, is not defective. If the cost is grossly underestimated and the patient who signed the ABN then refuses to pay, an administrative law judge or a court may determine patient liability.

Note that if a beneficiary signs an ABN and agrees to be liable for pay-

Who Qualifies As An "Authorized Representative"?

Under certain circumstances (*e.g.,* a Medicare beneficiary who is incapable or incompetent), the beneficiary's authorized representative may sign the ABN. As defined in the ABN instructions, this is "a person who is acting on the beneficiary's behalf and in the beneficiary's best interests, and who does not have a conflict of interest with the beneficiary, when the beneficiary is temporarily or permanently unable to act for himself or herself." Note: This definition differs from Medicare rules on who may sign a claim when the beneficiary is incapable—see 42 C.F.R. § 424.36(b).

According to the ABN instructions, the following may qualify as an authorized representative:

- ❖ An individual authorized under state law to make healthcare decisions or exercise medical power of attorney;
- ❖ The spouse (unless legally separated), an adult child, parent, adult sibling, close friend (in that order of priority); or
- ❖ A disinterested third-party (such as a public guardianship).

CMS does not explain how to determine whether an authorized representative has any conflicts of interest with the beneficiary. The agency does note, however, that an individual who is an employee of a physician or a supplier that is delivering the ABN may have a financial conflict and thus would be precluded from acting as an authorized representative.

ment, you are not subject to Medicare charge limits (*i.e.,* fee schedule amounts and balance billing limits do not apply). The item or service may be considered the same as other non-covered items or services.

❖ *The Patient Refuses To Sign, But Requests Services Anyway*

In this instance, you may choose not to provide the service. Of course, the patient's health and safety, civil liability for harm to the patient, or state law may preclude this option. For example, state law may require that lab tests be performed regardless of the patient's ability to pay. Instead of refusing to perform the service, you may have a second person witness the beneficiary's refusal to sign the ABN, then furnish the service. Where there may be only one person on-site (*e.g.,* in a specimen draw station), a second individual may be contacted by telephone to "witness" the refusal to sign. This witness would sign the witness statement later.

Assuming the refusal to sign the ABN is properly witnessed, the beneficiary may be held liable for payment because he or she has notice of the expectation of Medicare payment denial. Under such circumstances, however, the beneficiary can only be held liable if you accept assignment. If you don't, the beneficiary cannot be held liable. (The reason for this distinction lies in financial liability provisions of Medicare law know as "limitation of liability" [LOL] and "refund requirements" [RR]. When RR applies, the beneficiary cannot be held liable if he/she does not sign the ABN. When LOL applies, the signature is not mandatory, but the beneficiary may be held liable if he/she has notice that Medicare may deny payment.) *You must use the "GA" modifier on the CMS-1500 when you have a patient's refusal to sign an ABN properly witnessed and you accept assignment.*

6. Unique Challenges For Labs

Often a physician orders a laboratory test, collects the specimen and sends it to an outside lab for testing. The lab is responsible for billing Medicare for the test. The physician is not required to execute an ABN for a test for which payment to the lab is likely to be denied because the lab bears the financial risk if Medicare denies the claim. But because the physician is in a better position to execute an ABN during the office visit, CMS encourages the physician to work with the lab and obtain the ABN at the time of the office visit. If the physician executes an ABN, the lab need not obtain another one.

A lab may receive a specimen for testing that is time-sensitive but without an ABN and without ever seeing the beneficiary. If the beneficiary cannot be reached before the test is performed, the consequences are harsh if Medicare denies payment. The lab is financially liable and cannot collect from the beneficiary.

If the physician does not obtain an ABN, the lab may contact the patient to deliver it in person or provide notice by telephone, followed-up with a written ABN. If the patient cannot be reached, or refuses to sign, the lab may consider not performing the test (though some state laws may prohibit this).

The lab may choose to absorb the cost of the test, rather than risk a lawsuit if the patient is harmed because the test was not performed. As with any situation where free items or services are provided, however, the possibility of allegations of improper inducements must be considered.

A lab may receive a specimen for testing that is time-sensitive but without an ABN and without ever seeing the beneficiary. If the beneficiary cannot be reached before the test is performed, the consequences are harsh if Medicare denies payment. The lab is financially liable and cannot collect from the beneficiary.

In a situation where the lab contacts the beneficiary by telephone and the beneficiary initially agrees to sign the ABN, but later refuses to sign, the lab is financially liable if Medicare denies payment. The beneficiary is not liable because a disputed telephone notice does not constitute valid notice.

7. A Defective ABN Or Failure To Use An ABN

If the beneficiary did not receive an ABN or the ABN is defective, the beneficiary is generally not financially liable. For unassigned claims, the beneficiary must receive the ABN and sign it in order to be liable. For assigned claims, if there is evidence that before the item or service was furnished, the beneficiary knew (or should have known) that Medicare would not pay, then the beneficiary may be held liable, even in the absence of an ABN. For example, if the beneficiary previously received the same service (or substantially the same service) and got a Medicare payment denial, the beneficiary would have had notice that Medicare will not pay.

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■ **Gifts,** *from p. 1*

Health Insurance Portability & Accountability Act (HIPAA). Illegal remuneration can include waivers of copayments or deductibles and "transfers of items or services for free or for other than fair market value."

What's not illegal? Providers may give beneficiaries certain "inexpensive" gifts or services, other than cash or cash-equivalents. These gifts or services may not exceed $10 per item and $50 per beneficiary per year.

The law allows some exceptions, the OIG notes. Providers may offer beneficiaries more expensive items or services if they fit within one of five statutory exceptions:

- ❖ Waivers of cost-sharing amounts based on financial need.
- ❖ Properly disclosed copayment differentials in health plans.
- ❖ Incentives to promote delivery of certain preventive care services.
- ❖ Any practice permitted under federal anti-kickback law.
- ❖ Waivers of hospital outpatient copayments in excess of the minimum copayments.

The OIG is considering two other exceptions. One would allow providers to offer complimentary local transportation (but this would not cover ambulance or "luxury" transportation). The other would allow providers to offer free goods and services, including copayment and deductible waivers, for participants in clinical trials sponsored by the National Institutes of Health or another agency of the U.S. Department of Health & Human Services.

Gifts To Physicians

Both the federal anti-kickback statute and the Stark self-referral law apply in instances where a supplier, such as a laboratory or a pharmaceutical company, gives gifts to physicians, Kass says, though the Stark law does provide a limited exception.

Private Sector Promotes Ethics Guidelines

The American Medical Association recently launched a campaign to heighten awareness of guidelines on gifts to physicians from industry. AMA developed them in 1990. For a gift to be ethical under the guidelines, it has to meet three basic tests:

(1) Entail a benefit to patients.
(2) Be of nominal value (generally less than $100).
(3) Come with no strings attached.

It would be permissible, for example, for a physician to accept gram stain test kits, stethoscopes or other diagnostic equipment, as long as they are not of substantial value. "In considering the value, the relevant measure is not the cost to the company of providing the gift," says AMA. "Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market." Gifts of cash should not be accepted, AMA warns. The guidelines are online at *www.ama-assn.org/go/ethicalgifts*.

The Pharmaceutical Research & Manufacturers of America recently updated and re-issued its ethical code. The nine-point document covers many of the same issues as the AMA guidelines, including informational events, gifts to doctors and the independence of accredited CMEs. The document is online at *www.phrma.org/publications/2002-04-19.391.pdf*.

The federal anti-kickback statute prohibits individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by Medicare or Medicaid or any other federally funded program. While the statute does not contain any specific exceptions, intent is a key factor in determining whether a gift could be considered an inducement, Kass explains. "Sending a box of chocolates to a physician's office at Christmas probably would be safe. You have to ask yourself, 'Could this cause the physician to change referral patterns?' Probably not."

The OIG addressed inducements in a Special Fraud Alert on lab arrangements in 1994 and in a number of advisory opinions, including two in 1997: one on free services performed by clinical laboratories, the other on free prostate biopsy needles provided by labs to physicians. In general, the OIG has made clear that it views the provision of any free items by a seller to an actual or potential referral source as a potential violation of anti-kickback law.

The Stark II ban on physician self-referrals—which broadly prohibits physicians from making referrals for laboratory and other designated health services to entities with which they have a financial relationship—does have an exception for "non-monetary compensation." This permits a provider of a designated health service, such as a lab, to give a physician one or more non-cash gifts per year with an aggregate value of up to $300, so long as the gifts are not based on referrals or other business generated by the physician.

Gifts To Employees

The anti-kickback statute also can apply to gifts from a healthcare provider to employees of another provider if these employees are in a position to provide or influence referrals, according to Kass. For a provider's own, *bona fide* employees, there is a potential safe harbor under the anti-kickback statute and an exception under the Stark law that allow the employer to provide compensation to employees. This could include gifts, she says.

"If you're talking about giving a janitor a gift, I don't think you have

Providers Remain On Govt.'s Fraud Radar
Federal Officials Vow Vigorous Enforcement

Two top government officials took the stage at a recent Washington, DC forum to reaffirm their commitment to pursue federal healthcare fraud cases using the federal False Claims Act.

Thomas Scully, administrator of the Centers for Medicare & Medicaid Services, and Assistant Attorney General Robert McCallum said Sept. 30 that they continue to work closely together and with the HHS Office of Inspector General to uncover fraud and abuse in the healthcare industry.

McCallum noted, "We are committed to the fair and vigorous enforcement of the False Claims Act and its *qui tam* [whistleblower] provisions."

Both spoke at the fraud and compliance forum, sponsored by the American Health Lawyers Association and the Health Care Compliance Association on Sept. 29-Oct. 1.

Scully emphasized that CMS and the Justice Department have not let up on enforcement efforts, a concern voiced by Sen. Charles Grassley (R-IA).

In recent weeks Grassley has criticized these agencies for not using the False Claims Act and its 1986 amendments to the fullest potential (*see also p. 12*).

While the government supports compliance efforts by healthcare organizations, compliance programs themselves do not offer immunity to providers, McCallum said, particularly if the programs are poorly designed. "The fact that fraud has occurred despite a compliance program being in place speaks to the inadequacy of the program."

Scully said drug pricing issues and improprieties in the Medicaid and Medicare drug rebate area are near the top of the government's priority scrutiny list. His agency is concerned about federal drug reimbursement based on the average wholesale price (AWP) provided by pharmaceutical manufacturers, an issue the HHS OIG also addresses in its draft compliance guidance for these manufacturers, released Sept. 30. Critics say the pharmaceutical companies manipulate the AWP to increase their customers' profits.

"It's abuse of the taxpayer dollar," Scully said. "If Congress doesn't fix it, we'll rigorously use our regulatory authority to fix it."

■ **Gifts,** *from p. 9*

a problem. If you're talking about giving a gift to a physical therapist who could generate business, there might be a problem. Again, you have to look at whether the gift could induce someone to change his or her referral patterns," says Kass.

Have Clear Policies On Gifts

Kass recommends that healthcare providers have clear policies in place, detailing what is and what is not acceptable in terms of giving and receiving gifts. While most large providers probably have such policies as part of their compliance program, smaller providers may not, she notes.

"Some small physician practices might think it's not a problem if a vendor throws a nice lunch during the holidays and brings little gifts throughout the year. But if it adds up to more than $300, it could be a problem under the anti-kickback statute and certainly is a problem under Stark."

Resources

- Julie Kass: 410-685-1120
- OIG special advisory bulletin, "Offering Gifts and Other Inducements to Beneficiaries," online at *http://oig.hhs.gov/fraud/docs/alertsandbulletins.SABGiftsandInducements.pdf*.

Filing Deadline Nears For Requesting HIPAA Extension

Entities covered by HIPAA (the Health Insurance Portability & Accountability Act of 1996) have until this Oct. 15 to file for an automatic one-year extension to achieve compliance with HIPAA final standards for electronic healthcare transactions and code sets. Extension requests may be submitted either electronically or on paper.

Providers submitting a request along with a plan for achieving compliance will have until Oct. 16, 2003, to meet the standards.

A model form and related instructions for requesting the extension are online at *www.cms.hhs.gov/hipaa/hipaa2/ascaform.asp*.

Covered entities include health plans, healthcare clearinghouses and healthcare providers that transmit health information in electronic form.

Providers that fail to file an extension request and are not in compliance as of this Oct. 15 (the original compliance date) could face penalties of $100 per occurrence, up to $25,000 per year.

"I don't think HHS will pursue it, but I do think it's worth filing the request, especially since it takes only about 15 or 20 minutes," says attorney Rafael Olazagasti with O'Connell & Aronowitz (Albany, NY).

Resource

- Rafael Olazagasti: 518-462-5601

Coming In 2003: 12 New CPT Lab Codes

Twelve new CPT codes for clinical laboratory tests addressing such conditions as heart failure, cystic fibrosis, herpes simplex and cervical cancer will become effective Jan. 1, 2003. Final Medicare fees for these codes are to be announced in early November when the 2003 lab fee schedule is unveiled.

In preparing to establish fees, the Centers for Medicare & Medicaid Services held a public meeting last August to obtain recommendations from interested parties, including medical and lab-related associations, test kit makers and the public. The agency released its tentative payment decisions last month, allowing several weeks for further public comment. CMS generally agreed with recommendations from the public forum (see summary online at *http://cms.hhs.gov/paymentsystems/hcpcs/clinlabpay03.asp.*).

Below are tentative CMS fee determinations (note: numbering of the CPT codes has yet to be finalized).

CODE	DESCRIPTOR	TENTATIVE FEE	NATL CAP 2002
Chemistry			
8388X	Natriuretic peptide	Cross-walk to 84588	$46.91
8430X	Sodium; other source	Cross-walk to 84300	$6.72
Hematology			
8500X	Blood count; auto diff WBC count	Cross-walk to 85027	$8.95
8503X	manual cell count (erythrocyte, leukocyte or platelet), each	Cross-walk to 85590	$5.94
8504X	platelet, auto	Cross-walk to 85595	$6.18
8538X	Fibrin degradation products, D-dimer; ultrasensitive (*eg*, for evaluation for venous thromboembolism), qual or semi-quant	Cross-walk to 85379	$14.06
Microbiology			
8725X	Virus isolation; including ID by non-immunologic method, other than by cytopathic effect (eg, virus specific enzymatic activity)	Cross-walk to 87253	$27.91
8726X	Enterovirus, DFA	Cross-walk to 87199	$16.58
8727X	Cytomegalovirus, DFA	Cross-walk to 87198	$16.58
Cytopathology			
8817X	Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, auto thin-layer prep; screening by auto system, under physician supervision	Cross-walk to 88142, plus 8% of 88147	$28.00 (88142), $15.73 (88147)
8817X	with screening by auto system and manual rescreening, under physician supervision	Cross-walk to 88142, plus 44% of 88148	$28.00 (88142), $21.00 (88148)
Other			
8905X	Leukocyte count, fecal	Cross-walk to G0026	$5.90

New guidance from the Centers for Medicare & Medicaid Services on implementation of the new national coverage policies for 23 frequently ordered lab tests, effective this Nov. 25, provides additional clarification on how "date of service" is defined.

According to Transmittal AB-02-129, issued Sept. 27:

- Date of service should be reported as the date of specimen collection.
- The person obtaining the specimen must furnish the date of collection for the specimen to the entity billing Medicare.
- For specimen collections that span more than a 24-hour period, the date of service should be reported as the date the collection began.
- For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives.

CMS also notes that it will consider granting a grace period of up to 12 months from Nov. 25 for claims with dates of service on or after that date to accommodate any provider system changes required by the policy changes or clarifications resulting from the provisions of the rule.

Entities that wish to request a grace period to permit additional time to implement computerized changes must contact their carrier or intermediary in writing on or before Nov. 25. The request must include a description of the system changes, actions the entity has taken, a workplan with a timeline, dates when tasks will be performed and the date the entity will be able to implement the changes fully.

Transmittal AB-02-129 is online at *http://cms.hhs.gov/manuals/pm_trans/AB02129.pdf*

Have a compliance question you'd like answered? E-mail it to Kimberly Scott, managing editor, at kimscott@yahoo.com.

The Back Page

News-At-A-Glance

Doctor Gets 14 Years: A family practice physician convicted in February of 20 counts of healthcare fraud and seven counts of mail fraud received a 14-year prison sentence Sept. 11. Felix Vasquez-Ruiz, sole owner of Health Corporation 2000 Inc. (Chicago, IL), was found guilty of a false billing scheme that defrauded various private medical insurance companies of at least $2.5 million from 1996 through 1999. As part of the fraud, he allegedly performed medically unnecessary tests on patients, including nerve conduction tests that sometimes involved painful electrical shocks to patients' arms and legs. He also must pay $4 million in restitution.

Pathologist Pleads Guilty: A Florida pathologist faces up to 10 years in jail and a fine of $250,000 for illegally submitting claims to the Florida Medicaid program and private insurance companies between January 1996 and October 1999. Dr. Leonard Walker pled guilty on Sept. 3 to charges that while working as a licensed pathologist at Lawnwood Regional Medical Center in Fort Pierce, he illegally submitted claims for examinations of placentas resulting from births at the hospital. The U.S. Department of Justice alleged that Walker examined placentas more than a month after the mother and baby had been discharged from the hospital; thus, the exams were no longer medically necessary or appropriate. Sentencing is set for Jan. 9 in Fort Pierce.

Cardiologist Faces Prison: An Illinois cardiologist faces up to 18 years in prison and fines reaching $750,000 for his involvement in a fraud scheme in which he not only performed unnecessary and potentially risky cardiac procedures on dozens of patients, but also claimed to have provided care for patients after they died. Krishnaswami Sriram, from suburban Lake Forest, pled guilty on Sept. 19 to one count each of mail, healthcare and tax fraud. As part of the plea agreement, Sriram admitted that, from around September 1996 through March 2001, he improperly billed Medicare, Medicaid and private insurers for tests, services and procedures he never performed.

False Claims Act Scrutiny: Sen. Charles Grassley (R-IA) has called on the Senate Judiciary Committee to review the 1986 amendments to the federal False Claims Act (FCA), citing concerns over how they are being applied. In a letter to Judiciary Committee chairman Patrick Leahy (D-VT), Grassley noted, "Judicial circuits are split on several important facets of the Act. The Supreme Court itself has issued a ruling that narrows application of the Act by granting states sovereign immunity from whistleblower suits." Further, he pointed out, whistleblowers have complained that the *qui tam* process is too slow. Grassley plans to introduce "further refinements and improvements" to the FCA.

Use of the Act against healthcare providers has been particularly contentious. Under pressure from Congress and the hospital industry, the Justice Department formulated prosecutorial guidelines on how it would use the Act. Hospital groups had blasted the government for using the threat of harsh FCA fines to coerce individual hospitals into settling, rather than fighting, lab unbundling allegations.

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