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Perspectives on health care legal issues

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Know the plan

OIG's 2006 work plan can help you avoid hot spots

Every year, the Department of Health and Human Services' Office of Inspector General (OIG) publishes its annual work plan. The OIG's goal is to identify perceived vulnerabilities of government programs and promote improvement, efficiency and effectiveness, but providers can use the plan to identify and prioritize corporate compliance risk areas.

The 2006 plan includes a number of hospital and physician "hot buttons." Some are recurring OIG themes; others mark new concerns.

Medicare hospitals

The OIG identified several concerns pertaining to hospitals that treat Medicare patients and thus receive reimbursement from Medicare.

Payment for observation vs. inpatient admissions for dialysis services. The OIG learned that hospitals admitted patients for dialysis treatment that lasted 24 to 48 hours, although the stays were noted as observation rather than treatment. The Centers for Medicare and Medicaid Services (CMS) requires that physicians' orders clearly state whether the level of care required is "admission to inpatient status" or "admission to observation status." Observation services of up to 48 hours are paid hourly, whereas inpatient services are paid at a much higher rate under diagnosis-related groups (DRGs). The OIG is attempting to determine whether hospitals are accurately documenting patient status.

Inpatient prospective payment system wage indices. Another OIG goal is to determine whether hospital and Medicare controls are adequate to ensure accuracy of hospital wage data reporting. Inaccuracies can lead to incorrect DRG reimbursement. The OIG cautions that wage indices are vulnerable to inaccuracy because they may be significantly skewed by

single-hospital reports in many metropolitan statistical areas. The OIG did not elaborate as to why the sampling may lead to inaccuracies.

Inpatient rehabilitation facilities payments. The OIG is also concerned that payments to inpatient rehabilitation facilities under the prospective payment system don't comply with laws such as regulations concerning interrupted stays.

Rebates paid to hospitals. This is the second year in which the OIG will determine whether hospitals are properly identifying purchase credits as separate line items in their Medicare cost reports. OIG staff will visit several large vendors to ascertain the amounts of rebates they paid in a given year. The OIG will then review sample cost reports to determine if the rebates were properly credited.

Hospital reporting of restraint-related deaths. This is a critical concern for the OIG — cited in every work plan since 2001. In 2006, the OIG will assess hospitals' compliance with 1999 Medicare rules that require reports on patient deaths that may have been caused by restraints or seclusion.

Unbundling of hospital outpatient services. The OIG will determine the extent to which hospitals and other providers are submitting unbundled claims for outpatient services that should be bundled. Unbundling is the practice (forbidden by federal regulations) of submitting separate bills to maximize the reimbursement for various tests or procedures that are required to be billed together.

Medicare physicians

The OIG identified a number of areas in which it will look at physicians who are reimbursed for treating Medicare patients.

Billing service companies. The OIG has indicated for two years that it will review the relationships between billing companies and the providers who use their services to determine the impact of the arrangements on billings.

Ordering physicians excluded from Medicare. For three years running, the OIG has voiced concerns about the extent of services ordered by physicians who are excluded from federal health care programs and the related amounts paid by Medicare Part B. These physicians are generally precluded from ordering or performing services for Medicare beneficiaries.

Payment to providers for initial preventive physical examination. As of 2005, new Medicare beneficiaries are covered for an initial preventive physical examination (IPPE), including a screening electrocardiogram. Under a new health code, G0344, physicians may claim higher payment for IPPEs, and in some cases may submit claims for exams they conducted on existing patients who were not Medicare beneficiaries at the time, but who subsequently became eligible for Medicare. The OIG will evaluate the impact of IPPE coverage on Medicare payments and physician billing practices.

"Long-distance" physician claims. For four years, the OIG has been reviewing Medicare claims for face-to-face physician encounters in which there is significant distance between the practice setting and the beneficiary's place of residence. Beneficiaries with ongoing illnesses that require skilled care aren't expected to travel long distances from home. The OIG will confirm that services were accurately reported.

OIG plan goes beyond hospitals

In addition to its hospital-related priorities, the OIG's 2006 work plan includes sections related to many other areas of patient care, including Medicare home health and skilled nursing facility (SNF) services.

Regarding Medicare home health services, the government will monitor the frequency and geographic concentration of outlier payments to home health agencies. The OIG will also look for patterns of noncompliance with certification standards among home health agencies, and examine trends and patterns in survey and certification deficiencies.

Nursing homes, too, will be studied for survey and certification deficiencies. This priority reflects findings in a 2002 report, when the OIG found that the proportion of nursing homes cited for deficiencies, the total number of deficiencies, and the key categories of quality-of-care–related deficiencies had all increased since 1998.

More investigations expected

Each year, the OIG increases its efforts to prevent health care fraud. Its Office of Investigations (OI) studies individuals, facilities or entities that bill Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes, and other false claims. It also investigates business arrangements that violate the federal antikickback statute.

In 2006, the health care community can expect new safe harbor exemptions relating to the Medicare Modernization Act. Safe harbors specify various payment and business practices that would not be treated as criminal offenses under the antikickback statute. Also expected are continued enforcement of the patient antidumping statute and the possible exclusion of "several

thousand providers" from participation in federal health care programs.

Learn the rules

Although these are some of the OIG's hot issues for 2006, providers should become familiar with the entire work plan to avoid possible problems. Taking time to read and understand OIG priorities can be instrumental in focusing your ongoing compliance efforts. The full 2006 work plan is available online at http://oig.hhs.gov. <

OIG says Part D may not blend with PAPs

Organizations that want to offer patient assistance programs (PAPs) for Medicare Part D enrollees must proceed with care to avoid running afoul of federal antikickback statutes, according to the Department of Health and Human Services' Office of Inspector General (OIG).

The OIG looked at whether the federal antikickback statute would be implicated if organizations, such as pharmaceutical manufacturers, were to offer PAPs to help subsidize cost-sharing obligations for Part D beneficiaries. Providers should understand the types of PAPs that pass so they can better answer questions and point beneficiaries to much-needed assistance with Part D cost-sharing obligations.

Enrollees no longer qualify

PAPs have long provided financial assistance to those without drug coverage. The new Medicare Part D program offers broad coverage for outpatient prescription drugs, but, according to an OIG special advisory bulletin released last fall, enrollees may no longer qualify for PAPs.

Part D enrollees who don't qualify for Medicare income-based subsidies and/or various state or private pharmacy assistance programs will incur cost-sharing obligations such as deductibles and copayments. Pharmaceutical manufacturers want to offer PAPs that subsidize those cost-sharing obligations.

Steering clear of antikickback rules

Recognizing the importance of ensuring continued access to drugs for beneficiaries of limited means, the OIG issued a special advisory bulletin on PAPs, and offered less-risky alternatives to PAPs that may be found to violate the antikickback statute.

The federal antikickback statute makes it a criminal offense to offer, pay, solicit or receive remuneration for business reimbursable by federal health care programs, including Medicare and Medicaid. "Remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

It's a criminal offense to offer, pay, solicit or receive remuneration for business reimbursable by federal health care programs.

Subsidies illegal

Manufacturers that subsidized cost-sharing amounts would be in violation of the antikickback statute, because subsidies have the potential to steer beneficiaries to particular drugs. Thus, manufacturers would be offering something of value to encourage beneficiaries to use their products.

How can manufacturers legally use PAPs to help Medicare Part D enrollees? The OIG offers several safe alternatives, including:

Independent charity PAPs. Pharmaceutical manufacturers can make donations to independent, *bona fide* charities that provide cost-sharing subsidies for Part D drugs. There would be few antikickback concerns so long as:

- No improper control is exerted over the charity,
- The charity awards assistance independently and without regard to the pharmaceutical manufacturer's interests or the enrollee's choice of product, provider or Part D drug plan,
- Assistance is based on a reasonable and consistent measure of financial need, and
- The pharmaceutical manufacturer doesn't tie donations to the number of subsidized prescriptions for its product.

PAPs operating outside Part D. PAPs may provide free drugs to financially needy Medicare Part D enrollees outside of the Part D benefit. This would allow an enrollee to participate in a PAP as long as he or she didn't submit Part D claims for PAP-covered drugs. The assistance could not be counted toward the enrollee's total out-of-pocket or total Part D spending.

Coalition-model PAPs. Another option allows pharmaceutical manufacturers to join together to offer financially needy Part D enrollees a card or similar vehicle entitling them to subsidies for their cost-sharing obligations. The risks of illegal inducement would be reduced if, among other things, enrollees paid a portion of their drug costs out-of-pocket.

Bulk replacement models. Bulk replacement models involve pharmaceutical manufacturers providing in-kind donations in the form of free drugs to entities that dispense drugs to qualifying, uninsured patients. Such programs would violate the federal antikickback statute, however, if drug recipients were in a position to generate federal health care program business for the donor manufacturer.

In analyzing a potentially abusive practice, the OIG would consider how the program was structured and whether safeguards were in place to protect beneficiaries from being steered to particular drugs based on providers' or suppliers' financial interests.

Know the risks

The OIG's goal in drafting the bulletin was to help Part D enrollees transition from pharmaceutical manufacturer PAPs to less-risky programs. The key to averting antikickback liability is to be knowledgeable about the dangers and to take steps to avoid them. <

Translation required?

Understanding patient communication mandates

Health care providers and their patients must be able to communicate effectively, or quality of care may suffer. That can be problematic when providers and patients don't speak the same language. Title VI of the Civil Rights Act of 1964 states that you are probably obligated to translate for patients who don't speak English well.

Title VI antidiscrimination provisions have historically been construed to prohibit conduct that has a disproportionate effect on people with limited English proficiency (LEP). That means you have a

Title VI obligation to translate, but the extent of your obligation depends on several factors.

4-factor test

The following four factors determine your translation obligation:

1. The number or proportion of LEP persons you could serve,
2. The frequency with which LEP individuals come in contact with your services,
3. The nature and importance of your services, and
4. The resources available to the recipient and their costs.

The more important your services are, and the greater the possible consequences of the contact, the more likely it is that you'll be required to provide translation. You should, therefore, consider whether communication-based barriers could have serious or even life-threatening implications for your LEP patients.

If your activities or services are both important and urgent (such as information and consent for emergency surgery), you're more likely to be required to provide relatively immediate language services. If the activities are important but not urgent (such as elective surgery for which a reasonable delay will not adversely impact the patient's health), you can probably delay language services for a reasonable time. What is "reasonable" is determined by the circumstances. If the activities or services are neither important nor urgent, you may not need to provide language services at all.

Built-in flexibility

If you must provide translation services, Title VI gives you some flexibility in deciding what to provide. You may provide services that are consistent with your financial means. A large hospital, for example, may have full-time translators on staff, while a small hospital may contract for such services on an as-needed basis. In addition, you have substantial flexibility in determining the appropriate mix of oral vs. written services and in deciding whether to translate an entire document or provide just a summary. Whatever you decide, document the decision-making process.

One caution: It may be convenient to use a patient's family, friends or co-workers as interpreters, but you cannot require them to do so. Additionally, you must consider the nature of the situation and weigh concerns over competency, confidentiality, privacy and potential conflicts of interest against convenience. In any case, give patients the option of having a third-party interpreter provided at no charge.

Another factor to consider is whether you must translate vital documents such as consent, complaint and intake forms; written notices of eligibility criteria and/or changes in benefits; legal notices; and notices advising LEP individuals of free language assistance.

Safe harbors

The Office for Civil Rights considers two elements as safe harbors in enforcing Title VI claims. You can use the same elements to determine when to translate vital documents:

1. You must supply written translations of vital documents for each eligible LEP language group that constitutes 5%, or 1,000 people, whichever is less, of the population eligible for or likely to be affected or encountered by your services, and,
2. If there are fewer than 50 people in a language group that constitutes 5% of the population for your service area, you don't have to translate vital written materials — instead, you must provide written notice in the group's primary language of the right to receive competent oral interpretation of those written materials, free of cost.

Analyze your service area in light of these elements and you'll know whether translation is required.

Meet your obligations

Your obligation to translate documents or provide interpretation depends on the four-factor test, but you should be prepared to offer translation quickly when necessary. You also should have vital documents translated in compliance with the safe harbor.

Finally, while informal interpreters are allowed, you must exercise discretion in using them, and always notify patients of their right to an interpreter at no charge. <

Don't waver on waivers

How you can legally help needy patients

The Department of Health and Human Services' Office of Inspector General (OIG) has published several communications related to waiving copayments and deductibles, otherwise known as cost-sharing amounts. While such waivers can be problematic under federal law if they are routine, there is a long-standing exception for financially needy patients.

The federal antikickback statute prohibits providers from giving or receiving anything of value in exchange for referrals of business payable by a federal health care program, such as Medicare or Medicaid. But it doesn't expressly prohibit waiving copayments and deductibles.

Get out of the routine

The problem arises if one purpose of the waiver is to generate business payable by a federal health care program. Medicare cost-sharing amounts may be waived so long as:

- The waiver isn't offered as part of an advertisement or solicitation,
- The party offering the waiver doesn't routinely waive copayment or deductible amounts, and
- The waivers follow a good-faith effort to determine that the individual is in financial need or reasonable collection efforts have failed.

According to the OIG, a good-faith determination of financial need may include consideration of the local cost of living; a patient's income, assets and expenses; a patient's family size; and the scope and extent of a patient's medical bills. Thus, a financial need determination isn't limited only to indigence but can include other reasonable measures of financial hardship.

Avoid exclusion

The OIG may exclude providers from participating in federal health care programs if they submit claims for amounts that are substantially more than their usual charges. You aren't required to charge everyone the same price, or to offer Medicare or Medicaid your best price, but you cannot routinely charge Medicare or Medicaid substantially more than you usually charge others.

Establish objective, appropriate financial need guidelines for your service area. You should apply the guidelines uniformly, and periodically reassess them in light of changes in financial status in your region and patient base. Lastly, use reasonable measures to document your determinations of financial need.

Follow the rules

It's still permissible to waive copayments and deductibles for financially needy Medicare and Medicaid patients. It's just important to do so in accordance with federal guidelines.

A message to our clients and friends:

Hall Render is pleased to provide you with this issue of ***Practical Health Law***. This newsletter will be sent to you bi-monthly compliments of our health law attorneys; each issue will also be housed in the **Articles and Newsletters** section of **www.HallRender.com**.

We understand the value of good information when making sound business decisions. ***Practical Health Law*** is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you'd like to see addressed.

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