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For Hospitals, Laboratories and Physician Practices

Fraud Risks Need to Be Re-Examined in Face of Reform, Says IG

New payment and health care delivery models require a fresh examination of fraud and abuse risk, according to Daniel Levinson, inspector general of the Department of Health and Human Services (HHS). Levinson gave the keynote address at the Healthcare Compliance Association's Annual Compliance Institute.

According to Levinson, compliance professionals should be asking questions focused on transparency, quality, and accountability as they prepare for health care reform. "Are you prepared to operate in a more transparent health care system? Are you focused on quality as a compliance issue? Is your organization prepared for greater accountability?" Levinson asked attendees.

The Patient Protection and Affordable Care Act of 2010 (PPACA) contains numerous provisions that encourage the evolution of delivery and payment models designed to improve quality and introduce new efficiencies through greater integration, collaboration, and coordination among providers, noted Levinson.

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Plans to Sell OTC Genetic Test Kit on Hold After FDA Raises Concerns

Plans by Pathway Genomics of San Diego to sell an over-the-counter genetic test kit at Walgreens drugstores nationwide has been put on hold pending clarification of whether the test requires approval from the Food and Drug Administration (FDA).

Walgreens had planned to begin selling the Pathway Genomics Insight Saliva Collection Kit at most of its nearly 7,500 stores nationwide in mid-May. The product, which was expected to sell for $20 to $30, contains a small saliva collection kit, instructions, and a postage-paid envelope that customers could use to send their sample back to the Pathway Genomics laboratory. Customers could then order an individualized genetic health report for drug response ($79), prepregnancy planning ($179), health conditions ($179), or a combination of all three ($249).

According to an article published in the *Washington Post* on May 10, Pathway officials believe the OTC test does not require FDA

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Daniel Levinson, Inspector General of the Department of Health and Human Services.

Fraud Risks Need to Be Re-Examined in Face of Reform, *from page 1*

"As health care reform provisions are implemented, we at the OIG will need to work through the issues raised, as will your clients and organizations," he told participants. "Our mutual goal should be to develop such solutions as may be necessary to strike the right balance between protecting the integrity of the health care programs and fostering innovation that increases quality, efficiency and cost-effectiveness."

Levinson added that many of the provisions in the PPACA are consistent with the IG's five-principle strategy for combating fraud, waste, and abuse:

- **Enrollment:** Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment in health care programs;
- **Payment:** Establish payment methodologies that are reasonable and responsive to changes in the marketplace and medical practice;
- **Compliance:** Assist health care providers and suppliers in adopting practices that promote compliance with program requirements;
- **Oversight:** Vigilantly monitor the programs for evidence of fraud, waste, and abuse; and
- **Response:** Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.

The PPACA also increases funding for the Health Care Fraud and Abuse Control (HCFAC) program, which is the Office of Inspector General's (OIG) primary funding stream, noted Levinson.

"Historically, funding the HCFAC program has proven a wise investment," he said. "From its inception in 1997 through 2008, HCFAC program activities have returned more than $13.1 billion to the federal government through audit and investigative recoveries, with a return-on-investment of $6 for every $1 invested in OIG, Department of Justice (DOJ), and HHS activities through the HCFAC account."

> ***'Our mutual goal should be to develop such solutions as may be necessary to strike the right balance between protecting the integrity of the health care programs and fostering innovation that increases quality, efficiency and cost effectiveness.'***
>
> ***— Daniel Levinson***

Levinson also noted that the OIG is working closely with HHS and DOJ on the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a partnership that brings together high-level leaders from both departments so they can share information, spot fraud trends, coordinate prevention and enforcement strategies, and develop new fraud prevention tools. The OIG contributes its expertise to HEAT by analyzing data for patterns of fraud, conducting investigations, supporting federal prosecutions of providers who commit fraud, and making recommendations to HHS to remedy program vulnerabilities and prevent fraud and abuse.

Also as part of HEAT, the OIG is planning to conduct compliance training for providers in selected locations. "We are in the early stages of planning for this initiative, which will unfold over the next year, so stay tuned for further announcements about this exciting initiative," he said.

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Some Questions Compliance Professionals Should Ask as They Prepare for Health Care Reform

Transparency: Are you prepared to operate in a more transparent health care system?

» Does your organization have the right systems and technologies to meet new demands to collect, organize, track, retain, and report information and data accurately and completely?

» Do you have security and privacy protections in place for creating, transmitting, and storing data?

» Do you have systems in place to meet enhanced reporting and disclosure requirements applicable to your industry segment?

Quality: Are you focused on quality as a compliance issue?

» Do your clinicians understand that quality is a compliance concern and that quality of care is increasingly integral to payment?

» Do you have systems that will ensure that charting, collection, and reporting of quality data and clinical documentation are accurate, complete, and sufficient to justify payment?

» Are you present during conversations and involved in decisions about quality in your organization?

» Does your compliance department have the expertise to address quality-related compliance issues?

» Are your board of directors and management informed about the heightened role of quality of care under health care reform?

Accountability: Is your organization prepared for greater accountability?

» Do you have a compliance plan in place? If not, is your organization prepared to create and implement one?

» Do you know with whom your organization does business?

- Does your organization have affiliations with excluded, suspended, or Medicare debt-owing individuals and entities?
- Are you prepared to meet new requirements for background and licensure checks?
- Are the persons furnishing services through your organization qualified to do so?

» Are you focused on identifying and addressing new fraud and abuse risk areas that may arise as your organization becomes involved with new payment and delivery systems (such as medical homes, accountable care organizations, bundled payments, and value-based purchasing)?

- For example, are you thinking about risk areas such as inappropriate stinting on care, "cherry picking" patients, "lemon dropping" patients, gaming of payment windows, and misreporting of quality or performance data?
- Will you have safeguards in place to address these and other risks?
- Will compliance be part of the conversation as your organization contemplates new business and reimbursement arrangements?

» Is your organization addressing its increased compliance and quality responsibilities under health care reform?

- Are managers, staff, and contractors aware of their responsibilities?
- Are your training systems robust enough to support a new learning curve?

» If you represent a private insurer or employer organization preparing to participate in new public programs (e.g., participating on the exchanges or in the temporary employer retiree reinsurance program), does your organization have systems in place to ensure compliance with applicable program requirements?

» Do you have systems in place to screen for improper claims before they are filed?

- Are you using data mining and other techniques and technologies to detect improper claims?

Excerpted from a keynote address delivered by Daniel R. Levinson, inspector general for the Department of Health and Human Services, at the Health Care Compliance Association's Annual Compliance Institute on April 19, 2010.

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New CMS Restructuring Will Allow Focus on Fraud, Beneficiary Services

A newly created Center for Program Integrity to monitor fraud will be part of the Centers for Medicare and Medicaid Services' (CMS) latest realignment that also will allow the agency to focus on beneficiary services and strategic planning, the agency said in a recent notice.

Following up on an e-mail sent to agency staff in February, CMS in a March 24 *Federal Register* notice laid out a new structure for its offices.

"Given the complexity and importance of CMS's programs, this realignment of existing functions positions CMS to consistently excel in serving our beneficiaries and strategically positions CMS for the future," the notice said. "Additionally, this effort ensures common core functions are under common executive leadership and share a consistent vision."

The new Center for Program Integrity will handle national and state Medicare, Medicaid, and Children's Health Insurance Program (CHIP) fraud and abuse issues. Duties include conducting audits, conducting policy reviews, developing strategic plans, and aiding the states.

Other offices created under the CMS realignment, and some of their responsibilities, are:

- the Office of External Affairs and Beneficiary Services, which will be in charge of beneficiary communication, evaluation of customer data for improving communication tools, and liaison with the states and advocacy groups;
- the Center for Medicare, which will be the "focal point" for formulation and implementation of national program policies and operations and will coordinate with the new Center for Program Integrity;
- the Center for Medicaid, CHIP and Survey & Certification, which will be in charge of policies and operations for the three programs in the title as well as the Clinical Laboratory Improvement Amendments (CLIA);
- the Center for Strategic Planning, which will focus on long-term plans and future program policy and proposals throughout the agency; and
- the Chief Operating Officer, which will have responsibility for facilitating the coordination and execution of policies and will oversee activities, monitor agency performance, and intervene as appropriate.

Obama Nominates Donald Berwick To Be Next Administrator of CMS

President Obama has nominated Harvard professor Donald Berwick to be the next administrator of the Centers for Medicare and Medicaid Services (CMS), a post that has been vacant since late 2006.

Berwick is a clinical professor of pediatrics and health care policy at the Harvard Medical School and the Harvard School of Public Health. He is also president and chief executive officer of the Institute for Healthcare Improvement, a Cambridge, Mass.-based not-for-profit organization that promotes the improvement of health care.

CMS has been without a permanent administrator since October 2006 when Mark McClellan left the agency. Kerry N. Weems served as acting CMS administrator from 2007 until the end of the Bush administration.

Berwick, whose name surfaced several months ago as a possible nominee for the position, must be approved by the Senate Finance Committee and the entire Senate before beginning his job. He would be assuming the job at the beginning of arguably the most challenging period facing the agency as it works to implement numerous provisions in the health care reform law.

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COMPLIANCE PERSPECTIVES

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Health Care Marketing—What Every Provider Should Know: Navigating the Health Care Regulatory Landscape

Marketing is an integral component of any business enterprise's efforts to sustain and expand its economic base. In a time of declining reimbursement, many health care providers recognize the import of engaging in various marketing activities in an effort to maintain or expand their businesses. However, in the health care industry, common marketing practices that are truly effective and legal in almost every other industry are often strictly prohibited.

The Anti-Kickback Statute

Entertainment and Gifts

The anti-kickback statute (AKS) is an intent-based statute that contains both civil and criminal penalties. Any arrangement in which anything of value is exchanged between a referral source and a third party in connection with the provision of services paid for by a federal program potentially implicates the AKS. Because marketing is inherently designed to cultivate business through the offering of incentives, many common marketing campaigns will fall within the ambit of the AKS.

Due to the breadth of the potential application of the AKS, the Office of the Inspector General (OIG) was required to develop "safe harbor" regulations designed to protect various payment and business practices. If an arrangement falls outside of the safe harbor it is not per se illegal but the facts and circumstances behind the arrangement must be carefully reviewed. Thus, health care providers should design their marketing campaigns with a view toward mitigating compliance risks.

In the health care industry, it has been a common practice for providers to entertain and offer gifts (and other services and items of value) to physicians and other persons in a position to refer or arrange for referrals. In a progressively more competitive environment, the pressure to increase revenues often leads providers to expand their networks of target referral sources, and marketing in the form of entertaining and providing gifts is often viewed as the means to do so. The OIG has issued compliance guidance in this area which provides that gifts, gratuities, and other entertainment activities trigger potential AKS risk when they involve parties in a position to refer services or influence referrals to the provider.

As a result, before engaging in these types of activities, providers should adhere to certain safeguards designed to minimize AKS risk. Below are some examples of procedural safeguards that should be implemented by health care providers when engaging in marketing activities that involve providing gifts to and/or entertaining referral sources:

- The provider's administration should be notified of all marketing activities with referring physicians (as well as other referral sources). This will allow the provider to coordinate, monitor, track, and evaluate such activities from a compliance perspective.

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- Providers should never provide referral sources with cash gifts. Any non-monetary gifts can never be tied to referrals, should be nominal in value, and should be tied to educational or business sessions.
- In the event that a referring physician (or other referral source) suggests or represents that referrals or continued referrals are conditioned upon the provider providing entertainment or gifts to such individual, the provider should immediately refrain from any marketing effort with that individual.
- Providers must not correlate marketing expenditures to the volume or value of referrals to the provider by the referral source.
- When entertainment takes the form of dining, the provider should spend a significant portion of time discussing business or education matters with the individual.
- The provider must be aware of the amount expended on entertainment, both in terms of any specific episode (e.g., dinner), and the aggregate expenditure on any single referral source during a year. Simply put, as the amount expended increases, the likelihood of being able to view the entertainment as an inducement to refer increases in proportion to the level of expenditures.

Marketing Representatives

In order to successfully implement certain marketing efforts, a growing number of health care providers are engaging marketing representatives (sometimes referred to as "physician liaisons") to visit physician (or other referral source) offices with the goal of building relationships with the staff. Health care providers should be mindful that their financial relationships (e.g., independent contractor and/or employment) with these marketing representatives also fall directly within the ambit of the AKS. Accordingly, these financial relationships should be structured in light of the applicable AKS safe harbors.

With respect to marketing representatives who are independently contracted, the agreement should be structured in light of the personal services and management contracts safe harbor. Among other requirements, this safe harbor mandates that the aggregate compensation paid to the representative be set in advance, consistent with fair market value in an arm's-length transaction, and not determined in a manner that takes into account any referrals. As a practical matter, this will prohibit the representative from receiving compensation based upon a percentage or patient commission mechanism.

However, if the health care provider employs (rather than independently contracts with) the marketing representative, the AKS provides more flexibility, as the employee safe harbor allows the health care provider employer to pay an employee any amount (including percentage-based compensation) for their employment services. The key is that this safe harbor only applies if the employee is truly a *bona fide* employee as determined by the Internal Revenue Service.

Internet-Based Advertisement Companies

Lastly, with respect to the AKS, health care providers that engage or are contemplating engaging Internet-based marketing or advertising companies to assist in expanding their footprint should also keep in mind that the financial incentives paid to these companies will trigger the AKS prohibition. Thus, health care providers should have these contractual arrangements reviewed for compliance with personal services and management contracts safe harbor as set forth above.

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Stark

Entertainment and Gifts

Stark is a broad prohibition that bans physician referrals of Medicare beneficiaries to entities with which they, or members of their immediate family, have a financial relationship for certain services itemized in the statute, referred to as "designated health services" (DHS). DHS include, among others, durable medical equipment (DME), physical and occupational therapy, laboratory services, radiology and certain other imaging services, as well as inpatient and outpatient hospital services.

For purposes of Stark, a financial relationship may arise from a compensation arrangement, which includes the provision of anything of value to a referring physician. As a result, providers that furnish DHS (e.g., lab, diagnostic imaging, or physical therapy services) that engage in marketing activities that target physicians or physician-owned entities, including providing entertainment or gifts to such physicians and/or entities, must be aware that such marketing activities directly implicate Stark. If Stark is triggered, and an exception is not met, a health care provider will be subject to severe sanctions, including denial of filing claims for those referred services, civil monetary penalties, exclusion from Medicare and Medicaid, and potential false claims act liability.

Stark includes an exception for "non-monetary" compensation that applies to certain marketing activities. Under this exception, providers that furnish something of value (e.g., meals, entertainment, noncash gifts such as tickets, etc.) to a referring physician up to an annual limit of $355 (amount for calendar year 2010) will be protected by this exception. This exception applies only if the compensation (1) is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring provider, (2) is not solicited by the provider or the provider's practice, and (3) does not violate the AKS or any other federal or state law regarding billing and claims submission.

As noted above, health care providers should implement certain procedural safeguards when engaging in marketing activities that involve providing gifts to and/or entertaining physician referral sources. This should include, in particular, those principles discussed above, including tracking and maintaining documentation regarding aggregate expenditures by the provider for every referring physician to ensure that the aggregate annual expenditure limitation is not exceeded. In the event that a provider accidently exceeds the limit (not to exceed 50 percent), the Stark law provides that the excess can be corrected by repayment of the excess by the referring physician within the earlier to occur of the end of the calendar year or 180 days from the date of such payment, whichever is first.

Conclusion

Given the complex health care regulatory framework, health care providers need to ensure that they adhere to certain procedural safeguards when engaging in marketing activities with referral sources. In practice, this should cover any and all activities involving, for example, entertainment activities and the offering of any gifts to referral sources. Although, from a business perspective, it is unrealistic for the substantial majority of health care providers to forgo (or dramatically reduce the scope of their) marketing efforts, by implementing certain safeguards (some of which were discussed above), they can meaningfully mitigate risks under the AKS and Stark that are inherently associated with marketing. Thus, if referral sources are approached correctly, providers can continue to pursue activities designed to develop their business and expand their relationships with referral (and potential) referral sources without engendering undue legal risks.

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Plans to Sell OTC Genetic Test Kit on Hold After FDA Raises Concerns, *from page 1*

approval because the analysis will be done at the company's lab. "Our understanding under the current regulation is this test does not have to have FDA approval per se," said David Becker, Pathway's chief science officer. "And we do not claim that it does."

But a May 10 letter from the FDA to Pathway founder and CEO James Plante indicates that the test may require FDA approval. The letter from James Woods, deputy director of patient safety and product quality in FDA's Office of In-Vitro Diagnostic Device Evaluation and Safety, states the Pathway's Genetic Health Report appears to meet the definition of a device as that term is defined in the Federal Food Drug and Cosmetic Act. Laboratory tests are considered medical devices and require approval by the FDA.

> ***'Our understanding under the current regulation is this test does not have to have FDA approval per se'***
>
> ***— David Becker, Chief Science Officer, Pathway Genomics***

"We have conducted a review of our files and have been unable to identify any [FDA] clearance or approval number for the Genetic Health Report," wrote Woods. "We request that you provide us with the FDA clearance or approval number for the Genetic Health Report. If you do not believe that you are required to obtain FDA clearance or approval for the Genetic Health Report, please provide us with the basis for that determination."

In a statement released after receiving letter, Pathway said, "We respect and understand Walgreens' decision, and we are communicating with the FDA about the test."

While other companies have been selling genetic tests online and some tests for paternity and ancestry have been sold in stores, the plan by Pathway Genomics represented the boldest move yet to bring genetic testing to the mass market. Consumer and industry groups have been calling on the FDA to regulate genetic testing more aggressively and some believe Pathway's action could prompt the FDA to increase, or at least clarify, its oversight of genetic tests.

Sharon Terry, president and CEO of the Genetic Alliance, an advocacy and research group, praised Walgreens' action, according to the *Post* report. "Walgreens is clearly acting in the interest of its customers by postponing the introduction of the Pathway product," she said. "The FDA, for its part, must be the guardian of safety and efficacy, all the while encouraging innovation and the benefits that genetics can bring to medicine."

ACLA Supports Physician Guidance

The American Clinical Laboratory Association (ACLA), responding to the Pathway controversy, issued a statement noting that it supports physician involvement and guidance in ordering genetic tests and using those results to diagnose conditions.

"When genetic services are marketed and delivered directly to the consumer—without important input before and after testing from a personal health care provider and genetic counselors—gaps in understanding can result in serious negative consequences," said ACLA in the statement. "In using or interpreting tests that are important for disease prevention, diagnosis, and monitoring, consumers should rely upon an ordering physician with whom they have a personal relationship, and results should not be communicated via long-distance consultations."

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Many direct-to-consumer genetic testing companies are not testing individuals for disease—they are testing for the propensity of developing disease conditions, added ACLA. This type of testing can be helpful and informative but requires enhanced communication between patient and health care provider so that meaningful action to reduce the chance of developing disease can be taken.

"ACLA opposes irresponsible direct-to-consumer testing—genetic or otherwise—and supports rigorous state and federal investigation of such testing to determine whether it is in full compliance with regulatory requirements," said the statement.

NIH to Establish Genetic Testing Registry

The National Institutes of Health (NIH) is creating a public database that researchers, consumers, health care providers, and others can search for information submitted voluntarily by genetic test providers, including clinical laboratories, test manufacturers, and entities that report and interpret tests performed elsewhere.

The Genetic Testing Registry (GTR) is to be developed with stakeholder input this year and is expected to be available in 2011.

Currently, more than 1,600 genetic tests are available to patients and consumers, but there is no single public resource that provides detailed information about them, NIH said. The new registry is intended to fill that gap.

Key Operational Facts

- **Working definition:** A genetic test is defined as "a test that involves an analysis of human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes and/or gene products (e.g., enzymes and other types of proteins), which is predominantly used to detect heritable or somatic mutations, genotypes, or phenotypes related to disease and health."

- **Voluntary participation:** Submissions will be voluntary. Those submitting will be solely responsible for the content and quality of the data they provide. The registry will incorporate quality assurance safeguards and checks against inadvertent submitter error, but NIH will conduct no further review. Test providers will be encouraged to provide explicit molecular information about the test they perform and to cite published support for their assertions to help the public evaluate the data.

- **Types of information sought:** A wide variety of information can be submitted regarding the breadth of available genetic tests—including what tests are available, indications for testing, and who offers the tests—and quality measures such as analytical validity, clinical validity, and clinical utility. GTR data will be integrated with other related NIH databases to facilitate research.

- **How to reference tests:** Each test in the registry will be assigned a unique accession number, allowing for uniform reference to tests across various entities, including scientific publications and electronic health records.

- **Data collection:** Testing information will be gathered and managed using an online submission system. Alternatives will be made available to those

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providers who are not able to access online systems.

- **No cost or charge:** Testing providers can submit information regarding a single test or multiple tests at no charge. Nor will there be a charge to access information contained in the registry.

- **Ordering a test:** The GTR will help health care providers and consumers determine what tests are available and provide contact information for test providers. The registry will also help identify health care professionals who can assist with the testing process and other resources such as referral information for community support groups and disease information.

- **Project oversight:** The NIH director's office will oversee the GTR project, which is to be developed by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH. Updates on the Genetic Testing Registry are available at *www.ncbi.nlm.nih.gov/gtr/*.

GAO Report Recommends CMS Monitor Effects of Bundled Dialysis Care Payments

It will be important for the Centers for Medicare and Medicaid Services (CMS) to monitor the effect of a new bundled payment system on the access to and quality of dialysis care for beneficiaries with an above-average cost of treatment, the Government Accountability Office (GAO) said in a recent report.

"CMS's preliminary plans for monitoring the effects of the new payment system build on existing initiatives, but it is unclear whether CMS will monitor the effects on the quality of and access to dialysis care for groups of beneficiaries," the report stated.

The report, *CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System* (GAO 10-295), was made public on the GAO Web site April 30 but is dated March 31.

The report was requested by Reps. Pete Stark (D-Calif.), chairman of the House Ways and Means Health Subcommittee, and John Lewis (D-Ga.), chairman of the House Ways and Means Oversight Subcommittee. Bundled payments will drive more efficient provision of quality care, and Reps. Stark and Lewis in a joint statement said they requested the report to assess whether there are unique factors that would affect continued access to care under the new payment system, particularly for vulnerable populations.

Medicare covers dialysis for most individuals with end-stage renal disease (ESRD). According to the report, CMS currently divides dialysis and related services into two groups—one group that is paid for under a single payment and a second group in which services are paid for on a per-service basis. The first group includes dialysis treatment and associated routine services such as nursing, supplies, and equipment.

The separately billable services include injectable ESRD drugs as well as services such as laboratory tests and supplies that are used during the course of dialysis. Injectable ESRD drugs accounted for about 86 percent of Medicare expenditures on all separately billable ESRD services in 2007, the report stated.

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Since providers can receive more Medicare payments for prescribing more injectable ESRD drugs, GAO said it and others "have raised concerns that paying for this care on a per-service basis creates an incentive to use more of these drugs than necessary" and can contribute to unnecessary Medicare spending.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to implement a new expanded bundled payment system for dialysis care beginning in January 2011, which includes injectable ESRD drugs. The report noted CMS has stated that it will have a comprehensive monitoring strategy in place by January 2011.

Monitor Beneficiaries

According to the report, "questions have been raised about this new payment system's effects on the access to and quality of dialysis care for certain groups of beneficiaries, such as those who receive above average doses of injectable ESRD drugs."

For example, the GAO report found that Medicare spent $782 per month on injectable ESRD drugs per African American beneficiary, which was about 13 percent more than the average across all beneficiaries on dialysis and was also higher than for other racial groups. Similarly, monthly Medicare spending per beneficiary with additional coverage through Medicaid was about 6 percent higher than the average across all beneficiaries on dialysis.

The new bundled payment system for dialysis care has the potential to improve the efficiency of care delivery, in part by reducing the financial incentive to use more injectable ESRD drugs than are necessary, the report stated. However, if the new payment system causes providers to consistently experience financial losses when treating beneficiaries with above-average costs, then some beneficiaries could face problems accessing dialysis care or with the quality of that care.

Groups of beneficiaries with above-average costs of dialysis care, whether related to clinical or demographic factors, may be more vulnerable to these types of problems, GAO stated.

"Therefore it will be important for CMS to monitor the effect of the new bundled payment system on the access to and quality of dialysis care for these beneficiaries—which is consistent with previous work on the need for such monitoring under other bundled payment systems in Medicare."

GAO recommended that the monitoring should begin as soon as possible once the new bundled payment system is implemented and be used to inform potential refinements to the payment system.

CMS Response, Lawmakers' Concerns

In written comments on a draft of the report, CMS agreed with the GAO recommendation and noted that it is planning to actively monitor the effects of the new bundled payment system on all ESRD beneficiaries, including those with above-average costs.

CMS said that it plans to have a comprehensive monitoring strategy in place when the payment system is implemented on Jan. 1, 2011. CMS also said it plans to use its existing data sources to examine overall trends in care delivery and quality to help the agency ensure that beneficiaries continue to receive quality care under the new payment system. CMS stated that it "would use its existing infrastructure, including the ESRD networks, for quality oversight in the ESRD facilities."

The report is available at www.gao.gov/new.items/d10295.pdf.

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CHANGES TO SENTENCING GUIDELINES AFFECT COMPLIANCE OFFICERS:

Amendments to the U.S. Sentencing Guidelines sent to Congress April 30 include a change designed to encourage corporations, including health care organizations, to allow their compliance and ethics officers to report directly to their boards of directors as part of an "effective compliance plan" that will justify a reduced criminal sentence. The amendments contain changes that apply to what are known as the organizational sentencing guidelines and that adopt a new application note to the Commentary to Section 8B2.1—Effective Compliance and Ethics Program that details seven steps concerning what it takes to qualify for a reduction in sentencing because of such a program. The new note also fleshes out the seventh step: what it means to have "responded appropriately" once misconduct has occurred. It provides that the organization should take reasonable steps to remedy the harm resulting from the criminal conduct and that an organization should assess the compliance and ethics program and make modifications as necessary to ensure the program is effective. The final amendments will take effect Nov. 1 unless Congress acts to override the commission's action before then.

COURT PROVIDES GUIDANCE ON MEDICAL RECORD SEARCH WARRANTS:

The New Hampshire Supreme Court, seeking a balance between medical privacy and law enforcement, on May 6 issued instructions governing issuance of search warrants for privileged medical records (*In re Search Warrant for Medical Records of C.T.*, N.H., No. 2009-208). Under the new procedure, hospitals, or medical providers must comply with a search warrant within a reasonable time by producing the records under seal for a review by a trial court. The trial court then will give the patient and provider an opportunity to object, and the state will be required to demonstrate its "essential need" for the information contained in the record. The new procedure created by the court seeks to "resolve the tension between well-established law governing search warrants and the statutory protection afforded the physician-patient privilege" under state law, the court said.

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