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New Work Plan Targets Provider-Based Status; OIG Roadmap Has Some Surprises

It looks like scrutiny of provider-based entities will escalate over the next two years because the HHS Office of Inspector General (OIG) is reviewing them from all angles, according to its new Work Plan for fiscal year 2009, released Oct. 1, the first day of the federal government's fiscal year. OIG will assess whether inpatient and outpatient facilities and hospital-owned physician practices that bill Medicare under the provider-based designation comply with CMS requirements. Provider-based status generates more Medicare reimbursement, so noncompliance could lead to overpayments. Lawyers say they hope OIG will stick to substantive noncompliance, and not demand repayments based on a few mistakes, considering the many hoops hospitals jump through for provider-based status.

The 2009 Work Plan is a "comprehensive" list of the projects OIG plans to work on during the year because they've been deemed "most worthy of attention," OIG says. HHS and the Office of Management and Budget help refine it before publication. The Work Plan also serves as a blueprint for compliance monitoring because it's a litany of the government's perceptions of Medicare and Medicaid vulnerabilities. But OIG notes development of the document is a dynamic process, subject to modification.

As the watchdog agency, OIG audits and evaluates every HHS-funded program, including the National Institutes of Health. But 80% of the Work Plan is devoted to

Scorecards Demonstrate to Board Members How Compliance Activities Reduce Risks

Some health systems are using scorecards as a shortcut to giving executives and board members a lot of information about what's being accomplished by the compliance program and where the organization is at risk. And as leaders increasingly want to see the cause-and-effect relationship between the two, experts say the new generation of scorecards will have to show leadership teams and boards the correlation between compliance and risk reduction/performance improvement.

"Because of their oversight role, the board needs reasonable assurance that things are good, or if bad, they want to know what we are doing about it," says attorney José Tabuena, vice president of integrity and compliance at MedicalEdge Healthcare Group, Inc., a very large Dallas-based physician management organization. To meet their demands, compliance officers use metrics to identify and prioritize risk. But board members don't want or need to see the voluminous data that metrics yield.

Metrics in this context refers to data about the effectiveness of compliance program activities and the status of risk areas. Because management has long understood that what you measure is what you get, there's been a push toward developing easier-to-read scorecards and dashboards. Data are gathered continuously from both inside the

compliance program (e.g., investigations, compliance committee meetings, billing and coding audits, etc.) and perhaps outside (e.g., OIG audits and Medicare repayments). The data are used to monitor the program over time and identify the legal, regulatory and other minefields that are ripe for corrective action.

The data should be boiled down for boards, says attorney Eric Klavetter, compliance and privacy officer for Mayo Clinic, a 1,900-physician/scientist-based practice in Rochester, Minn. One option is user-friendly scorecards (see scorecards, pgs. 3 and 4). "Scorecards help you put meaning to the metrics," Tabuena says. Scorecards provide a structure for organizations to routinely report progress, or lack of it, as time marches on. And they minimize jargon, a premium for board members who may tune out at the sound of phrases like "RACs" or "one-day stays," Klavetter says.

Scorecards list major compliance-program activities and key risk areas, with a symbol to indicate the organization's performance in each area. Usually this is a red light (which means the area needs immediate improvement), a green light (the area is at or above expectations) or a yellow light (which means some improvements are needed). The compliance officer, in partnership with the applicable management team, will explain corrective action plans for the red-light items, Tabuena and Klavetter said at a recent Health Care Compliance Assn. audioconference and in interviews with *RMC*.

Risk areas are nothing new, although using metrics and showing the results through scorecards allow companies to analyze and reprioritize as they face new challenges or uncover errors. *But there's a twist:* It's no longer enough with many boards to report on what the compliance office has done. Metrics should be used to connect the dots between the organization's investment in compliance and the return on that investment.

Board Focus Has Shifted to Outcomes

"Five years ago or so, board metrics were more about the fact that we had 500 hotline calls in the first half of the year and trained 90% of employees and did X number of audits," Tabuena says. "Now it is shifting toward the outcome — and how your activities are changing the outcome."

When building metrics, Klavetter says you apply two important principles:

(1) Engaging management to understand the structure you are trying to establish: "The structure is meant to standardize the prioritization and risk-rating process," he says. For example, if you use a scorecard, the meaning behind the colors red, green and yellow must be universally understood. "You engage management and line staff to help create an inventory of metrics that can be captured, and use that process with the understanding that metrics will get rolled up to leadership, which fulfills the second goal," Klavetter says.

(2) Empowering board members to know what the risks are and enlist their support for action plans to improve weak areas and ensure accountability and responsibility.

Klavetter explains that Mayo has a "risk portfolio with many programs in it." Inside the programs are projects that a particular team may oversee. For example, one program is government payer compliance. Projects within include the incident-to and teaching-physician rules. "We go through an initial assessment of a project and determine what controls we have in place," he says. Then the project is evaluated according to a set of criteria, including staffing, resources, infrastructure and strategic plan implementation. "We look

for opportunities to improve and assess our practices," Klavetter says. Recommendations are brought to physician leadership teams, which lead the effort to mitigate the risk with the help of compliance.

These metrics are then rolled up into scorecards, which give boards the bottom line graphically — which is appealing considering the volume of information the board is expected to absorb. Klavetter says he realized the value of getting across the main points quickly when he arrived to give the board a report and saw that he was one of numerous people sitting outside the boardroom, waiting for their sliver of time.

But don't mistake the simplicity of the scorecard for a lack of sophistication of the underlying material or the people who will review it, he adds. Scorecards open a dialogue between compliance, management and the board. "It creates a structure to interact on very complex topics," he contends.

It's important to avoid too much detail with the board, though, adds Klavetter. At first, the members may not want to hear about the incident-to rules or respiratory DRGs until they better understand the context. "Let the board go up a learning curve in a deliberate way with management's assistance," he explains.

Sample Hospital Compliance Scorecard

This sample compliance scorecard is an example of the kind of metrics that health systems can use to track outcomes of compliance interventions in key risk areas (see story, p. 1). Metrics are now emphasizing what compliance achieves, not just that compliance elements are in place and functional (e.g., not how many coders attended advanced coding compliance training, but that training reduced coding errors), says José Tabuena, vice president of integrity and compliance for MedicalEdge Healthcare Group, Inc., a very large Dallas-based physician management organization. He supplied the compliance scorecard, though it was developed by a health system. Contact Tabuena at jtabuena@med-edge.com.

	Points
Quarter and Date:	
Compliance Oversight:	5
Executive compliance committee minutes — validated agreed upon discussions (quarterly, annual, etc.)	
Compliance Documentation:	5
Policies reviewed and revised in accordance with policy guidelines	
Compliance risk policies evaluated and modified based on risk assessment	
Compliance Training and Communications:	5
• Satisfactory percentage of new employees trained timely	
• Satisfactory percentage of existing employees trained timely	
• Satisfactory percentage of employees receiving risk-based education	
• Compliance communications disseminated in accordance with compliance communication plan	
Compliance Monitoring, Reporting, and Inquiries:	5
• Hotline/helpline issues closed within established time frames	
• Hotline/helpline corrective action validated in accordance with agreed-upon procedures	
• Employee ethical climate survey scores maintain agreed-upon percentage	
• Risk assessment conducted in accordance with agreed-upon procedures	
• Audits conducted in accordance with agreed-upon timelines	
Disciplinary Actions:	5
• Audits reveal employee/management completed annual performance reviews at agreed-upon percentage	
Responses to Detected Offenses:	5
• Exit interviews conducted in agreed-upon percentage	
• Refunds/corrective action documented/disciplinary actions documented	
Compliance Outcome:	70
Compliance coding audit error rate	

Rating				Green, Yellow, Red
Compliance Coding Audit Error Rate Point Key			**Overall Evaluation Key**	
0 – 5%	50 Points		80 and above	Green
6 – 9%	40 Points		60 and above	Yellow
10 – 15%	30 Points		59 and below	Red
16 – 20%	20 Points			
21 – 25%	10 Points			
25% +	0 Points			

So what kinds of metrics are behind the red, green and yellow lights of the scorecard? Until recently, scorecards reported more one-dimensional data — what are known as "effort metrics." Examples are how many coders or physicians attended coding education and whether every employee completed HIPAA training. But now the board wants to know whether the training improved

coding and whether privacy violations are down because of all the money invested in HIPAA compliance. Tabuena, who helped organizations assess compliance programs when he was a consultant, says he's had clients who track the number of privacy complaints received and allegations substantiated and then try to correlate these data with the implementation of HIPAA policies and training. "Most boards don't care as much anymore about effort metrics," he says. "If training doesn't make a difference as far as behaviors and performance, to them it doesn't matter, and they won't pay attention to that data."

Coding is trickier because you have to trend improvements over time and segment it by specialty and, if applicable, geography, says Tabuena. For example, before coders or physicians attended coding training, accuracy was at X percentage, but now it's risen to Y percentage. "We try to show the impact of compliance program activities. Trending is a type of metric," he says.

There Is Down Side to Scorecards

There are some disadvantages to scorecards, Tabuena and Klavetter say. For example, "there's no standard or easy scoring formula," Tabuena says. To some degree it's a matter of trial and error. How you weigh metrics against each other to attain a score is a challenge. If the scores match up to your instincts about an entity, that's a good sign. But "you'd be concerned if a facility is having problems and it scores yellow or green in every area," he says. That raises questions about whether the scoring method is accurately capturing what you want to measure.

In addition, expectations must be realistic, Klavetter says. "Maybe management and the compliance officer thought a risk could be reduced in 90 days, but it's going to take six months," he says. "You have to be as scientific or data-driven as possible."

Also, if the elements on the scorecard are too easy, the scorecard may not be a true representation of risk. And if the elements are too hard, it may make the compliance program look ineffective. In the end, each organization will need to define the approach that best fits its organization and culture, says Klavetter.

It also can be disconcerting to put the organization's weaknesses in such stark terms. There are always concerns that the performance doesn't improve as expected, but that may be the moment where leadership has a clear understanding of what risk it is assuming, he says. Another concern is that the scorecard could be legally discoverable in an enforcement action. That's a potential cost of scorecards, but the benefit outweighs the cost because it shows an organization's proactive intent to identify and mitigate risk, says Klavetter. They also assist

Another Sample Scorecard

Most scorecards use red, green and yellow circles as a quick way to report on the status of compliance program activities and key risk areas (though the colors are just stated in the versions below). Which are in good shape? Which are ripe for corrective action? This scorecard was supplied by Eric Klavetter, compliance and privacy officer for Mayo Clinic in Rochester, Minn. Contact him at klavetter.eric@mayo.edu.

Topic	2006	2007	2008
Revenue Cycle Last Updated — October 2007			
Identify and Self-Report Overpayments	Green	Yellow	Yellow
Coding Reviews	Yellow	Red	Green
Education	Yellow	Yellow	Yellow
Confidentiality — Last Updated May 2007			
Patient Complaints and Patient Rights	Green	Green	Green
Access and Authorization Controls	Red	Yellow	Yellow
Unintended Disclosure of Protected Health Information	Yellow	Yellow	Yellow
Accounting Controls (ICE) and Audits — Last Updated May 2008			
Internal Audits	Yellow	Yellow	Yellow
External Audits	Green	Green	Green
ICE (internal controls evaluation)	Green	Green	Green
Regional Practice — New Program			
Site:		Yellow	Yellow
Project: Electronic Medical Records Implementation			To be determined
Process: Drug Diversion		Red	Yellow
Research — Last Updated August 2007			
Implementation of New Systems	Red	Yellow	Yellow
Clinical Billing in Research	Red	Red	Green
Auditing/Monitoring	Red	Red	Green
Environmental Protection Agency and FDA — Last Updated October 2007			
Hazardous Waste	Yellow	Yellow	Green
Good Tissue Practices	Yellow	Green	Green
Clinical Laboratory Improvement Amendments	Red	Yellow	Yellow
Education — New Program			
Student Issues		Yellow	Yellow
Financial		Yellow	Yellow
Extramural Activities		Red	Green

These are examples and do not reflect Mayo Clinic's actual numbers or performance. See story on p. 1 for scoring methodology.
Red = does not meet expectations.
Yellow = satisfactory, needs improvement.
Green = meets expectations.

in resolving issues in a timely manner. Tabuena suggests having a process that helps ensure that significant issues are routed for legal review when appropriate, and that takes training and judgment.

Contact Tabuena at jtabuena@med-edge.com and Klavetter at klavetter.eric@mayo.edu. ✧

CMS Reveals Bulk of MUEs; Now Hospitals Can Screen Own Claims

CMS announced Oct. 1 that it has published most of the medically unlikely edits (MUEs) — 9,700 of them — ending the mystery of why many hospital outpatient claims are rejected. Hospitals can now install the edits in their billing systems so they can catch their own errors rather than reworking them after the fact.

"We have always felt like we were in the dark or guessing at what Medicare was looking at. Now we know," says Wendy Trout, compliance officer for Well-Span Health in York, Pa.

MUEs are designed to improve the accuracy of Medicare claims payments by hunting down a service that has been reported too many times or otherwise makes no sense. The edits check the number of times that a provider or supplier reports a service for the same patient on the same date. Services are reported on claims using HCPCS/CPT codes along with the units of service (representing the number of times the service is provided). OIG has detected a lot of overpayments stemming from services billed with too many units of service.

CMS first implemented MUEs in Jan. 1, 2007, with edits for about 2,600 HCPCS/CPT codes and then updated it quarterly. Now, all at once, CMS has revealed the majority of existing MUEs. They apply to all Part B claims.

The edits are based on a number of factors, including anatomic considerations, HCPCS/CPT code descriptors, CPT instructions, CMS policies, nature of service/procedure, and clinical judgment, says Kim Brandt, director of the CMS program integrity group, in a letter to providers and suppliers.

Brandt cautions providers to continue to bill only for services that are medically necessary. "CMS is concerned that providers will incorrectly interpret MUE values as utilization guidelines," she writes. "MUE values do NOT represent units of service that may be reported without concern about medical review."

Trina Jayne, senior medical review analyst at Well-Span, says it's a big relief that CMS is posting the MUEs because for a long time, providers were unsure about what they were. "I am very excited they even published anything. CMS has always been very vague about this,"

she says. She speculates that the reason for this was CMS didn't want to reveal its program-integrity secrets and let providers figure out how to do an end run around the edits.

But Jayne contends that the MUEs are overkill. Some claims get denied unfairly, she asserts, which means providers have to appeal them. WellSpan appeals denials for claims only above a certain dollar threshold to ensure winning an appeal is not actually a losing proposition dollarwise, she says.

For example, it's common to bill multiple pathology units (tests) off one specimen. But an MUE would block payment because there is only one CPT code for that type of pathology, and it doesn't distinguish between the types of pathology tests that warrant multiple tests and the types that don't, says Jayne.

WellSpan immediately installed the MUEs in its billing system. Its claims scrubber will subject claims to the 9,700 edits before they are processed and sent to Medicare. When claims are blocked by the edit, WellSpan's coding specialist will review them and, if necessary, correct the claims before submitting them to Medicare.

CMS, though, is still not going to publish certain MUEs. "CMS will not publish all MUE values that are 4 or higher because of CMS concerns about fraud or abuse," Brandt says. Jayne speculates that again CMS doesn't want to disclose too much about how it catches on when people are trying to game the system.

In her letter, Brandt also says that some MUE values may be different than the ones originally posted. They have been modified "based on the data refinement using the 100% submitted claims data from a six-month period in 2006."

Read more at the CMS MUE Web page at www.cms.hhs.gov/NationalCorrectCodInitEd/08_MUE.asp#TopOfPage. The MUEs also can be downloaded from there. Contact Jayne at tjayne@wellspan.org and Trout at wtrout@wellspan.org. ✧

GAO: Reduced Fees for Imaging Did Not Lead to Fewer Services

Concerns within the imaging provider community that fee reductions for certain imaging services would lead to physicians ordering fewer tests have not been realized, says a Government Accountability Office (GAO) report (GAO-08-1102R) posted Sept. 26.

Lawmakers had become concerned with the rapid growth of Medicare Part B spending as a whole, but particularly with imaging, which was the fastest-growing service within Part B. They included in the Deficit Reduction Act (DRA) a provision that said fees for certain

imaging services covered by the physician fee schedule could not exceed payments for the services under the outpatient prospective payment system (OPPS).

Medicare spending for imaging services paid for under the physician fee schedule more than doubled between 2000 and 2006, GAO reported in June (GAO-08-452), with services performed in offices rising from 58% to 64%. The report also noted that physicians obtained an increasing share of their Medicare revenue from imaging services. In-office imaging spending per beneficiary varied across geographic regions of the country, which suggests that not all services were necessary, it added. GAO suggested that CMS consider other management practices of imaging services, such as prior authorization *(RMC 7/21/08, p. 8)*.

Physician organizations and other groups claimed that the fee reduction would make physicians less willing to provide the services for beneficiaries. The cap was implemented for tests performed on or after Jan. 1, 2007. Congress asked GAO to look at the impact the DRA had on the use of and spending on physician imaging services in the fee-for-service (FFS) program.

GAO found that Medicare expenditures for the services declined in 2007, but use of imaging continued to rise. The OPPS was the main factor in the spending decline. Other factors that led to the spending decline include a decrease in size of the FFS population and fee-schedule changes. Specifically, GAO found that Medicare expenditures for the services from 2000 to 2006 increased 11.4%, but declined 12.7% in 2007. Yet utilization continued to increase in 2007 at a rate of 3.2%, although GAO acknowledges that is slower than the 5.9% rate from 2000 to 2006. In comments included in the GAO report, CMS says the findings are consistent with CMS's own data,

which indicate a 20% reduction in payments for imaging services that are subject to the OPPS cap. CMS also said it is relieved that the findings indicate that beneficiaries still have access to the services, but that it is still concerned about the high volume of the tests and whether they are necessary.

Read the GAO report at www.gao.gov/cgi-bin/getrpt?GAO-08-1102R. ✧

Work Plan Stresses Provider Status

Medicare and Medicaid. The section for hospitals (Part A and Part B) has some themes running through it. In addition to the provider-based status issue, OIG seems focused on cost reports, quality of care and payments outside the DRG, says Millie Johnson, institutional compliance officer for Texas Tech University Health Sciences Center. And OIG is already making a foray into Medicare severity-DRGs (MS-DRGs), which had been in effect for only one year when the 2009 Work Plan was released.

OIG's scrutiny of provider-based status compliance could be intensive given how far-reaching provider-based requirements are, says Washington, D.C., attorney Andy Ruskin, who is with Morgan, Lewis & Bockius. The provider-based designation means an entity — whether it was originally a free-standing clinic, a physician practice or another hospital — becomes clinically and financially integrated into a (dominant) hospital, he explains. The entity has to meet a litany of requirements to qualify as provider-based, but one reward is extra reimbursement through the Medicare cost report, he says. And where there's extra reimbursement, OIG may perceive the potential for abuse — but not so much in this case, many experts believe, which is why the lawyers *RMC* interviewed find OIG's interest in provider-based entities a bit curious.

"The provider-based rules are tricky, detailed and subjective," says Boston attorney Larry Vernaglia, who is with Foley & Lardner LLP. "It's important for providers to get them right, and fundamental disregard for the provider-based requirements shouldn't be tolerated. But this should not get set up as a 'gotcha' regime."

In the first Work Plan item, OIG says it will review "provider-based status for inpatient and outpatient facilities," which refers to a hospital being a single entity while "owning and operating multiple provider-based departments, locations and facilities that were treated as part of the main hospital for Medicare purposes." OIG says it will "determine the potential impact on both the Medicare program and its beneficiaries of hospitals improperly claiming provider-based status for inpatient and outpatient facilities."

Ruskin says OIG seems particularly concerned about the potential for gaming Medicare when one hospital becomes the provider-based entity of another. But hospitals don't enter this arrangement lightly, he says. The two hospitals become a single hospital with two campuses. Because it requires clinical and financial integration, one hospital has to be dominant, and the smaller, provider-based entity will be subordinate to the other. That's politically hard to accomplish, and sometimes hospitals have to abandon plans to become provider based, he claims. Financial integration means, for example, there is a single cost report, and accounts are combined in one trial balance. Clinical integration may be thornier because of the sensitivity with physicians. There is one chief medical officer for both hospitals, and he or she is located at the dominant hospital (even if there is a CMO for both, one person has to be *numero uno)*. The clinical departments at both hospitals are essentially consolidated, with a medical director at the dominant hospital running the department. "You need to have a reporting chain from each of the departments on the provider-based site up through main provider site," Ruskin explains. "And the subordinate hospital's medical director still has to report to the chief medical officer of the main hospital."

Despite the challenges, some hospitals pursue provider-based status with a partner because of certain reimbursement advantages, he says. For example, a hospital with fewer than 100 beds is subject to a cap on disproportionate share hospital (DSH) payments. But if it crawls into the skin of another, larger hospital owned by the same company, the smaller hospital — which, as a provider-based entity, is now the second campus of the main hospital — is eligible for full DSH payments. "But it's not so easy to do this," Ruskin maintains. "If you never actually met the provider-based requirements for the subordinate hospital, the enhanced DSH payments to the subordinate hospital are at risk." That is what OIG has its eyes on. A lot of money is at stake.

Provider-Based Designation Will Be Verified

CMS will also look at hospital-owned physician practices with and without provider-based designation. Hospitals may collect more Medicare reimbursement for outpatient services in provider-based clinics under the outpatient prospective payment system than under the Medicare Physician Fee Schedule. But now OIG wants to know whether these provider-based clinics fulfill the requirements for the designation, what the impact is of Medicare paying more to provider-based clinics for the same services, and whether hospital-owned practices that aren't provider-based received inappropriate Medicare reimbursement.

OIG has been worried about provider-based entities for quite some time, says Vernaglia. In 1999, OIG issued a report on hospital ownership of physician practices citing the potential for abuse. Provider-based entities also are a risk area in the 2005 OIG supplemental compliance program guidance for hospitals.

But the lawyers who spoke with *RMC* contend that OIG may be barking up the wrong tree with the provider-based targets. For one thing, says Vernaglia, provider-based noncompliance doesn't really correlate to a billing overpayment. "It's not certain to me that OIG would even be right in demanding overpayments if it found a violation of provider-based status rules," he says. Those rules are analogous to Medicare conditions of participation, he says. "You don't collect overpayments when paint is peeling on the walls," he explains. In those cases, CMS typically pursues corrective action plans.

Ruskin adds that providers wouldn't just fake a provider-based relationship. "It's likely there is real substance to the provider-based designation. These arrangements are not just schemes for increasing reimbursement." And OIG was flat-out wrong when it stated in the Work Plan that CMS "grants" provider-based status to hospitals, he maintains. CMS regulations don't mandate CMS's pre-approval for provider-based designation, he says. However, if hospitals feel safer with the CMS imprimatur, they can voluntarily seek CMS's acknowledgment of their entity's provider-based status, says Ruskin. Just submit a request to the CMS regional office with documentation of clinical and financial integration and satisfaction of the other provider-based requirements, and "they will let you know," he explains.

Other Work Plan Targets

There are several other key observations about the Work Plan. One is how many items fall outside the DRG, Johnson says. Another is the way there seems to be a common theme underlying many issues. Among them:

◆ *Quality*: The Work Plan includes items on "Serious Medical Errors (Never Events); Oversight of Hospitals' Compliance with the Emergency Medical Treatment and Labor Act" and "Reliability of Hospital-Reported Quality Measure Data."

◆ *Cost reports:* A number of items on the Work Plan are really cost-report compliance issues, including: (1) "hospital and Medicare controls over the accuracy of the hospital wage data used to calculate wage indices for the" inpatient prospective payment system. In the past, OIG has found hundreds of millions of dollars in misreported wage data; (2) provider bad debt, which keeps rearing its head on cost reports; (3) Part A hospital capital payments; and (4) DSH payments. "If you haven't been auditing your cost reports, now is the time to start," Johnson says. "That should have been part of your compliance program for the hospital. Verify the information that is on there."

◆ *Non-DRG issues:* A biggie here is X-rays in the emergency department. ED physicians order X-rays and interpret them to treat the patient, but often they don't do a formal interpretation for billing purposes, says Johnson. Instead, the radiologist may document and bill for the professional-fee component. There are a couple of potential compliance risks here: In the past, OIG has indicated that the interpretation billed should be contemporaneous with the patient's treatment, so if the "official interpretation" is done after the patient is already released, there is a question of medical necessity for that billed interpretation, Johnson says. In other words, if the radiologist performs the interpretation after the patient has been treated by the ED physician and has left the ED, the only purpose at that point may be to provide quality oversight (and documentation in the medical record), she says. But Medicare doesn't pay for quality reads, she explains, so it may be considered a noncovered service. And if both the ED physician and the radiologist bill for X-rays in the ED, there could be double billing.

Other Part A and B hospital items on the Work Plan include a coding review of MS-DRGs one year into the new system, two inpatient psychiatric hospital reviews, a review of critical-access hospitals and a study of inpatient hospital payments for new technologies.

Medical Identity Theft

Johnson was intrigued to see "Medical Identity Theft in Medicare" in another section of the Work Plan. OIG will review CMS's measures to deter medical identity theft. For example, how does a provider know that the patient presenting for treatment with a Medicare ID card for Jane Smith is truly that beneficiary? And how does CMS know it was the real Dr. Steve Jones who filed $50,000 worth of Medicare claims last month under the National Provider Identifier for Steve Jones? "OIG may not feel the Federal Trade Commission's Red Flag Rules are sufficient," she says. The Red Flag Rules, which take effect Nov. 1, require creditors that hold consumer accounts "for which there is a reasonably foreseeable risk of identity theft" to implement an identity theft prevention program. "The program must include reasonable policies and procedures for detecting, preventing and mitigating identity theft," the agency says. This apparently applies to health care organizations that allow patients to pay over time.

Contact Ruskin at aruskin@morganlewis.com and Vernaglia at lvernaglia@foley.com. View the Work Plan at AIS's Government Resources at the Compliance Channel at www.AISHealth.com; click on "OIG's Work Plan." See Medicare Program Memorandum A-03-030 for a list of provider-based requirements. ✧

NEWS BRIEFS

◆ **The South Florida Health Care Fraud Strike Force charged 245 defendants with fraud totaling $793.4 million in fiscal year 2008, which ended Sept. 30,** the U.S. Attorney's Office for the Southern District of Florida said Sept. 30. Those numbers were up from both 2006, when 197 defendants were charged with fraud totaling $638 million, and 2005, when 111 defendants were charged with fraud totaling $138 million. Visit www.usdoj.gov/usao/fls.

◆ **On Sept. 30, OIG issued supplemental compliance program guidance for nursing facilities.** The updated guidance was prompted partly by changes in the Medicare reimbursement system. New risk areas include comprehensive care plans, sufficient staffing, appropriate medication management and resident safety. View the guidance at http://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf.

◆ **Drug maker Cephalon Inc. has agreed to enter a criminal plea deal and pay a total of $425 million in criminal fines and civil settlements to resolve allegations that it engaged in off-label marketing of three drugs resulting in false claims submissions to federal health care programs,** the Department of Justice (DOJ) said Sept. 29. Former Cephalon employees brought four whistle-blower lawsuits against the company, alleging that it promoted the drugs Actiq, Gabitril and Provigil for uses that the FDA had not approved. Cephalon pleaded guilty to one count of violation of the U.S. Food, Drug and Cosmetic Act. As part of the plea agreement, it will pay $40 million for a criminal fine and $10 million that "will be applied as substitute assets to satisfy forfeiture obligation," DOJ explains. In a separate civil settlement, the company will pay $375 million to resolve False Claims Act allegations. Cephalon also entered a five-year corporate integrity agreement (CIA) with OIG that requires the company to report payments to physicians on its Web site, among other things. The whistle-blowers will share more than $46 million of the settlement. In a prepared statement, Cephalon says it cooperated with the government throughout the investigations. It adds that its current compliance program already contains elements in the CIA and that "the strong compliance infrastructure now in place has improved the accountability of our employees and the transparency of our actions." Visit www.usdoj.gov.