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CMS Wraps Up Final Stark Rules On Physician Referrals

The good news for providers is that the final rules generally ease up on restrictions governing physician referrals and financial relationships, with some new provisions of interest to clinical labs

The long wait for a wrap-up of federal rules interpreting the Stark ban on physician self-referrals is over. On Mar. 26 the Centers for Medicare & Medicaid Services published the second and final phase of its rulemaking on the Stark statute restricting physicians from making Medicare/Medicaid referrals for designated health services (DSH) at healthcare facilities with which the doctor (or an immediate family member) has a financial relationship.

The Phase II rules are effective this July 26. Combined with previously issued Phase I final rules, they supercede 1995 rules applicable to prohibited lab referrals under Medicare, CMS says. The original Stark law, enacted in 1989, covered only Medicare lab referrals, but in 1993, the law was expanded to Medicaid referrals and, in addition to lab services, a host of other DHS. Among the highlights of the new rules:

Percentage Compensation: Physicians who work as independent contractors will benefit from the expansion of such ➥ *p. 2*

HHS Approves Drug Card Sponsors

The U.S. Department of Health & Human Services has released a list of sponsors approved to offer Medicare beneficiaries a prescription drug discount card, beginning this June 1. The program, authorized under the Medicare reform law, will run until a full Part D drug benefit debuts in 2006.

Of the approved sponsors, 28 are private entities, 43 are managed care plans. They may charge an annual enrollment fee of up to $30. They also must publish prices for the drugs they offer, provide access to a retail pharmacy network, operate call centers and be able to respond to beneficiary concerns. Pharmacy benefit managers on the list are anxious to build credibility with HHS and market share among seniors in anticipation of the full drug benefit, said Mark Merritt, president of the Pharmaceutical Care Management Association.

HHS says the cards can save beneficiaries 10% to 25% on prescription medications. At least some of the savings must come from manufacturer rebates. Low-income seniors will get a $600 credit and pay no enrollment fee. An estimated 7.3 million seniors will sign up, including 4.7 million eligible for low-income aid.

INSIDE *NIR*

Join in our ***Apr. 29 "hot topic" audioconference*** *to learn how to comply with changes in the Stark final rules on physician self-referrals.* *See p. 8 for time and registration information*

CMS Publishes Final Stark Rules, *from p. 1*

arrangements allowed under personal service and fair market value exceptions. CMS had contended that those based on fluctuating or indeterminate measures, or those that result in different payment amounts for the same services to the same purchaser, are not "set in advance." The agency dropped its opposition and modified the "set in advance" definition to clarify that the formula for calculating percentage compensation must be "established with specificity prospectively," must be objectively verifiable and may not be changed over the course of the agreement based on the volume or value of referrals or other business from the referring physician. CMS noted that, by statute, this limitation does not apply to group practices.

Productivity Bonuses: These can be paid to all physicians, whether employees, independent contractors or academic medical center physicians, for work they personally perform. Previously, only employed physicians were expressly permitted to get such bonuses. In addition, group practices may pay physicians in the group, whether independent contractors or employees, a productivity bonus based on "incident to" services. Group practices also can provide indirect bonuses and profit sharing that may include revenue from a DSH.

In-Office Ancillary Services: Under this exception, DSH must be furnished to patients in the same building where the referring physician provides regular medical services, or, in the case of a group practice, in a central building, as long as certain conditions are satisfied. This is to help ensure that the qualifying services are truly ancillary to the core medical practice and not a separate business enterprise. CMS has retained its previous definition of "central building" as relating to a single U.S. Postal Service street address. A mobile van or trailer used for lab tests wouldn't qualify. However, CMS changed its three-part test for verifying that the same building is used for physician services unrelated to DHS.

"By and large, [the final Stark rules] are good news for healthcare providers," says attorney S. Craig Holden with Ober/Kaler (Baltimore, MD), noting two provisions of interest to clinical labs:

- A new exception for certain arrangements that inadvertently fall out of compliance for reasons beyond the control of the DHS entity.
- An expansion of the lease exceptions to include month-to-month holdover tenancies or possessions that continue under the same terms and conditions as the original lease or rental agreement for as long as six months. This could help if there were paperwork problems for a lab that leases space from a referring physician.

He notes too that a professional courtesy exception is established, which means many labs may once again feel compelled to provide free tests that they had stopped offering for fear of anti-kickback violations. The new exception allows entities to extend professional courtesies such as free or discounted services to "a physician or a physician's immediate family member or office staff," if various conditions are met.

CLIA-Waived Tests: CMS declined to exclude these from the definition of covered clinical lab tests, saying that none of the CLIA waiver requirements would guard against overutilization or other abuse. Anyway, the agency noted, such tests furnished during an office visit would likely fit within the exception for in-office ancillary services.

Pap Smears: CMS declined to add diagnostic Pap smears to the exception for screening Pap smears and other preventive services.

The Stark interim final rules (with comment period) were published in the Mar. 26 *Federal Register*. A technical correction addressing reporting requirements, which were inadvertently not included, will appear in the Apr. 6 *Federal Register*.

Controversy Heats Up Over Medicare Reform Cost Estimates

The Bush Administration is on the defensive over allegations by Medicare's top cost analyst that his boss and top White House officials withheld from Congress his estimate that Medicare reform legislation would cost considerably more than Administration officials wanted to disclose. The Congressional Budget Office estimated that reform would cost $395 billion over 10 years. In enacting the bill, Congress authorized $400 billion over 10 years, an amount that the White House agreed to.

To the discomfort of GOP election strategists, more seniors disapprove of how the President is handling Medicare, and support is dropping among Americans of all ages, says a new USA Today/CNN/ Gallup poll, which suggests that the cost estimate conflict, Democratic attacks and public uncertainty are contributing factors

What wasn't disclosed were much higher cost estimates calculated early in the legislative debate by Medicare actuary Richard Foster. According to Foster, various versions of the bill would cost $500-$600 billion. The final estimate, $534 billion, was not made public until after Congress had enacted the reform bill.

Charges & Countercharges

At a Mar. 24 hearing of the House Ways & Means Committee, Foster said that during the reform debate on Capitol Hill, his boss, Thomas Scully, then head of the Centers for Medicare & Medicaid Services, forbade him from disclosing any of his estimates. Foster said he feared he would be fired if he did so and considered resigning, in part because Scully's deputy, Leslie Norwalk, assured him that withholding the estimates was within legal bounds. Foster said his staff persuaded him to stay on, arguing that his departure in these circumstances could impact the actuary office's long-term viability.

Administration officials have suggested that Scully was acting on his own, but Foster told lawmakers he believed the White House was involved in the decision to not disclose. Health & Human Services Secretary Tommy Thompson said the first time he saw Foster's $534 billion estimate was in January 2004, but Foster asserted that a $551 billion rough estimate dating back to June 2003 had made the rounds at HHS, the Office of Management & Budget, and the White House.

The controversy is troublesome to the GOP because the Bush re-election campaign has been touting Medicare reform, saying the President has delivered "the same Medicare, more benefits," including prescription drug coverage and expanded managed care options. Disclosing Foster's estimates could have threatened passage of the reform bill by sowing opposition among fiscally conservative House Republicans who objected to expanding the Medicare entitlement, but went along during an extraordinary three-hour roll call vote just to support the President (*National Intelligence Report, 25, 4/Nov. 25, '03, p. 1*). Disclosure too could have caused trouble in the Senate by convincing middle-of-the-road Democrats that the bill gave too much away in subsidies to drug makers and private health plans. Sen. Edward Kennedy (D-MA) has assailed the law as a sweetheart deal for business and a raw deal for seniors.

On the same day of the Ways & Means hearing, a number of Senate Democrats wrote to Attorney General John Ashcroft, asserting that Administration officials such as Scully may have violated two criminal statutes by blocking disclosure of Foster's estimates. Kennedy, Hillary Rodham Clinton (NY), Debbie Stabenow (MI) and Frank Lautenberg (NJ) signed the letter. Lautenberg added in a statement, "Hiding $139 billion in additional costs to the taxpayers so the President can get his flawed Medicare law passed is a breathtaking abuse of power."

Cost analyst experts point out that CMS and CBO estimates are just that—estimates—and make assumptions about new programs and the future. HHS Secretary Thompson noted that CMS and CBO had diverged by $50 billion in projecting the impact of the 1997 Balanced Budget Act, and both turned out to be wrong.

Why Is CMS Estimate So Much Higher?

The discrepancy between CBO and CMS projections reflects nothing more than an accumulation of differences in technical assumptions, Foster and CBO director Douglas Holtz-Eakin said at the Ways & Means hearing and at a briefing the next day on the Medicare and Social Security trust funds, hosted by the American Enterprise Institute. Compared to the CBO estimate, CMS figured $100 billion more for the Part D drug benefit, including:

- ❑ $32 billion more for the basic benefit, of which half stems from a 4% higher estimate of per-capita costs and half because CMS estimated 94% of eligible enrollees would participate, while CBO estimated only 87% would do so (mirroring the experience with Part B).
- ❑ $47 billion more for the low-income subsidy, because CMS assumes participation would begin immediately instead of ramping up over three years, would reach a 13-15% higher participation rate and would involve higher per-capita costs.
- ❑ $18 billion more in federal Medicaid spending due to a difference in estimated baseline spending on prescription drugs for beneficiaries eligible for both Medicare and Medicaid.

Big Reimbursement Shift Ahead?

There could be for clinical laboratories, physicians and other healthcare providers if projections by the Centers for Medicare & Medicaid Services hold up.

Currently, most Part B services for the vast majority of beneficiaries are reimbursed as fee-for-service. Under Medicare reform, CMS estimates, 32% will switch to the Medicare Advantage program, offering coverage under HMOs, PPOs and other private health plans, starting in 2006.

To capture this Medicare business, labs and other providers will have to compete on price and quality. But they won't be subject to fee-for-service rules and should save on billing and administrative costs associated with Part B.

The Congressional Budget Office has a much lower estimate, projecting that only 9% would move to managed care. Both CBO and CMS assume that a shift to MA coverage would increase federal spending (by $14 billion and $46 billion, respectively), though the Bush Administration argues that a more market-oriented Medicare would cut costs. CBO and CMS assume that many beneficiaries who switch will be in relatively low-cost, low-density areas where Medicare payments to MA plans and premium rebates will exceed fee-for-service rates.

Trustees Issue Insolvency Warning For Medicare Hospital Fund

Part B and Part D deficits to trigger sharp rise in out-of-pocket costs for beneficiaries

The Medicare Part A trust fund for hospital inpatient care will go broke by 2019, seven years earlier than expected just a year ago, while for the near term the Part B benefit and the new Part D drug benefit will require sharp premium increases, the Medicare trustees warned in their recent annual report.

The date for Part A insolvency has accelerated due to several factors, Medicare's chief actuary, Richard Foster, told an American Enterprise Institute audience on Mar. 25. These include higher payments to rural providers and Medicare Advantage plans, lower payroll tax revenue, higher benefit payments, and sicker beneficiaries.

The Part B supplementary insurance fund faces a major near-term deficit because of steps taken to prevent reductions in physician fees. Instead of a 4.4% cut for 2003, Congress raised fees by 1.6%. This led to a $10.3 billion deficit because the change occurred too late for the government to adjust beneficiary premiums. Another deficit looms for 2004. Congress approved a 1.5% fee increase vs. the 4.5%

New Medicare Cost-Cutting Weapon

Speaking at the same AEI meeting as Medicare actuary Richard Foster, the head of the Congressional Budget Office, Douglas Holtz-Eakin, highlighted an obscure provision in the Medicare reform law that could pressure lawmakers to slash program spending.

Starting in 2005, trustees must calculate if the difference between Medicare's dedicated financing sources and outlays will exceed 45% of total outlays in the next seven years. If so, the President has 15 days after the trustees' report is issued to send Congress a proposal to resolve the problem. Congress must act by that July. In this year's report, the trustees predict the 45% threshold will be reached by 2012. "And if there are continued physician updates, it's a lock that it will happen," Holtz-Eakin said.

scheduled cut. For 2005, the increase will also be no less than 1.5%, but the Centers for Medicare & Medicaid Services will have time to boost premiums accordingly. Foster projected they could go up 17%.

Outyear projections for Part B spending are unrealistically muted, Foster said, because, by law, they must reflect the assumption that the physician fee formula won't be changed. For 2006 through 2012, CMS projects a 5% reduction, but Foster says "it's not going to happen." The American Medical Association is lobbying Congress to change the formula to avert future fee reductions. The trustees' report is online at *cms.hhs.gov/publications/trusteesreport*.

New Medicare Chief Previews His Priorities

"[CMS] is a public health agency, it's not just about paying bills, it's about improving the health, the quality of care in this country," says the new head of the agency, Mark McClellan

In his first major outing as administrator of the Centers for Medicare & Medicaid Services, Mark McClellan, MD, PhD, sketched out his goals for restraining program spending without cutting fee schedules, while improving healthcare "so that people can benefit from the biomedical revolution already on the way."

Speaking at a Mar. 30 American Medical Association meeting in Washington, DC, McClellan, who prior to taking the helm at CMS was head of the Food & Drug Administration, emphasized the cost-cutting potential of switching from paper to electronic information systems, offering drug discount cards, promoting cheaper generic drugs and relying on new disease prevention and management paradigms. "We can do better than treat patients for costly and devastating complications that could have been prevented in the first place," he said.

McClellan drew hearty applause when referring to curbs imposed by the Medicare reform law on contractors' use of claims sample extrapolations to determine overpayments. He drew even more applause when he promised to work against physician fee cuts. "In the past, when costs go up, the practice has been to reduce physicians' reimbursement rates. I don't want to see that happen again. One of the tried and true ways that Medicare has always turned to when it can't find any better solutions to controlling costs is to reduce payment rates for health providers. I think we have run that string out as far as we can. We need to find a better way to get Medicare costs down without sacrificing quality." Referring to physician fee cuts ahead in 2006 under the statutory formula, McClellan added, "We're going to do everything we can under the law to reduce the size of that cliff."

He also praised AMA's campaign for medical liability reform, saying the current system threatens access to care and adds billions of extra costs to Medicare and Medicaid, while there is peer-reviewed empirical evidence that caps on damage awards, like those President Bush advocates, would save billions.

HIPAA Deadline Near For Updating Business Associate Contracts

HIPAA compliance continues to be a struggle, according to providers polled in a quarterly survey by HIMSS and Phoenix Health Systems in January. Nine months after the privacy rule took effect on Apr. 14, 2003, 20% were not compliant, and many others had yet to update business associate agreements

Healthcare providers and other entities covered by HIPAA—payers, clearinghouses and small health plans—have until this Apr. 14 to ensure that contracts with business associates conform to federal privacy requirements. Under HIPAA (the Health Insurance Portability & Accountability Act of 1996), privacy standards took effect on Apr. 14, 2003, but covered entities were granted an additional year to bring BA contracts into line with privacy regulations.

BA contracts must contain certain privacy safeguards for protected health information (PHI or individually identifiable health information). Business associates must agree to:

- ❑ Ensure that PHI will not be used or disclosed except as specified in the contract.
- ❑ Ensure that PHI is kept confidential.
- ❑ Report privacy breaches to the covered entity.
- ❑ Require their agents and subcontractors to comply with the same requirements that apply to business associates.
- ❑ Make PHI available to satisfy patients' rights.
- ❑ Make PHI available to satisfy HHS's right to investigate and enforce HIPAA.
- ❑ Return or destroy all PHI upon termination of the contract, if feasible.

Major Healthcare Exceptions

For healthcare providers, there are several major exceptions to the business associate standard. In these situations, a covered entity does not need a BA contract or other written agreement in place before PHI can be disclosed to a person or entity. This includes disclosures by a covered entity to a healthcare provider for treatment of the individual, according to guidance from the HHS Office for Civil Rights. For example:

- ❑ A hospital is not required to have a BA contract with the specialist to whom it refers a patient and transmits the patient's medical chart for treatment purposes.
- ❑ A physician is not required to have a BA contract with a laboratory as a condition of disclosing PHI for the treatment of an individual.
- ❑ A hospital lab is not required to have a BA contract to disclose PHI to a reference lab for treatment of the individual.

Other situations in which a BA contract is not necessary include:

- ❑ When a provider discloses PHI to a health plan for payment purposes, or when the provider simply accepts a discounted rate to participate in the health plan's network. A provider that submits a claim to a health plan, and a health plan that assesses and pays the claim, are each acting on their own behalf as a covered entity, not as the "business associate" of the other.
- ❑ With persons or organizations, such as janitorial or electrical services, whose functions or services do not involve the use or disclosure of PHI, and where any access to PHI by such persons would be incidental, if at all.

Tips On Compliance

"Most covered entities did an inventory of their business associate relationships before the April deadline last year, so this is a good time to go back and see if there are any remaining gaps," suggests healthcare attorney Reece Hirsch, a partner in the San Francisco office of Sonnenschein Nath & Rosenthal.

"Most covered entities, as they approached the deadline last year, put agreements in place with their major relationships, but often there are stragglers—small vendors, for example—and now is the time to make sure you've followed up on those."

In determining whether you need a BA contract with a vendor, ask yourself two questions, Hirsch advises: is the vendor performing a function on behalf of the covered entity, and is the vendor getting PHI in the course of the service?

Now's a good time too, he says, to consider how to modify BA contracts to comply with the HIPAA security rule that takes effect on Apr. 21, 2005 (see the *Federal Register*, Feb. 20, 2003). But he cautions about provisions relating to the reporting of security incidents. "I would advise putting these in a contract, but specifying that they don't become effective until the compliance date of the security rule. I suspect by the time that rolls around, we'll have some additional guidance."

CMS Offers Guidance On Specialty Hospital Moratorium

Many specialty hospitals are owned entirely or in part by physicians. The moratorium seeks to stem the outflow of profitable business lines to these facilities, a shift that community hospitals say puts them at a competitive disadvantage since they must provide such care, even at a loss

The Centers for Medicare & Medicaid Services has released guidance on how it will implement the 18-month moratorium imposed by Congress on physician referrals of Medicare/Medicaid patients to certain specialty hospitals. The moratorium, enacted in the Medicare reform law, applies to the "whole hospital" exception in the Stark self-referral law, which permits Medicare/Medicaid referrals by doctors who have a financial interest in an entire hospital, as opposed to a unit or department of a hospital.

The moratorium took effect last Dec. 8 (the date the Medicare reform law was signed) and expires June 8, 2005. It "grandfathers" specialty hospitals under development or in operation as of Nov. 18, 2003. This provision applies, CMS says, only as long as the number of physician investors has not since increased, the specialized services have not since changed, the number of beds has not since expanded by more than five (or 50%), and no beds have been added off the hospital's main campus.

CMS will only consider specialty hospitals to have been under development as of Nov. 18, 2003, if their architectural plans were completed, funding was received, zoning requirements were met, and necessary approvals were obtained from appropriate state agencies.

Those unclear on this point, CMS says, can request an advisory opinion, as provided under Stark self-referral rules. The rules address prohibited financial ties by ownership interest or compensation arrangements, health services subject to the ban and numerous exceptions. For more on the moratorium, see CMS Transmittal 62 (Apr. 2, 2004) at *cms.hhs.gov/manuals*. The CMS contact is Joanne Sinsheimer, 410-786-4620.

What's Affected?

Physician self-referrals to specialty hospitals, even in rural areas, that mainly provide cardiac or orthopedic care, surgical procedures or any other specialized services that CMS may designate. The agency said it would not designate any other services "at this time."

What's Not?

Physician self-referrals to psychiatric, rehabilitation, children's and long-term care hospitals, as well as cancer hospitals that are not paid under inpatient prospective payment.

♦ QUESTION *of the* M·O·N·T·H

How long must we keep records of our competency assessments for point-of-care testing? As part of the assessments, required for our hospital lab's CLIA accreditation by the College of American Pathologists, we give a test every year to more than 1,000 nurses who perform tests such as bedside glucose monitoring of diabetics.

CAP told us you must retain periodic competency evaluations and performance review records for at least the time from the previous inspection, which would be two years, or longer if state record retention requirements are more stringent. However, CAP considers written tests optional for competency verification. So you might want to consider revising your competency assessment process with an eye to reducing the associated paperwork. Much of the process can be accomplished through direct observation and review of existing records.

FDA Approves Rapid HIV Test Using Oral Fluid

The decision gives a market boost to test maker OraSure, which already makes an FDA-cleared rapid HIV-1/2 test, using blood samples. It also enables HIV to be caught at the point of care and treatment to begin promptly. An estimated 25% of the 900,000 HIV-infected people in the U.S. are unaware that they carry the virus

The Food & Drug Administration on Mar. 26 approved a rapid HIV-1 test kit manufactured by OraSure Technologies (Bethlehem, PA) that reports results from an oral fluid sample in as little as 20 minutes and is more than 99% accurate to screen for antibodies to the virus that causes AIDS. Until now, all rapid HIV tests required use of blood to get such fast results. The newly cleared OraSure test can be stored at room temperature and requires no specialized equipment.

The original version of this rapid test—OraSure's OraQuick Rapid HIV-1/2 Antibody test—has been approved to detect antibodies in blood and has a CLIA waiver. The new OraSure test is approved for use on oral fluid, but is limited to detection of HIV-1 antibodies; nor is it approved to screen blood donors. While not yet CLIA-waived, FDA's acting chief, Lester Crawford, DVM, PhD, has urged OraSure to apply. If the test can prove safe and easy to use in the waived lab setting, where the company's fingerstick blood test is already in use, "then more people will be likely to be tested for HIV. Also, risk to healthcare workers will be greatly reduced since they will not be exposed to blood," he said.

When the test device is used, the person being tested takes the device, which has an exposed absorbent pad at one end, and places the pad above the teeth and against the outer gum. The person then gently swabs completely around the outer gums, both upper and lower, one time around. The tester then inserts the device into a vial containing a solution. If HIV-1 antibodies are present in the solution, two reddish-purple lines will be displayed in a small window on the device. Positive results require confirmatory testing.

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Final Stark rules on physician referrals and financial relationships have just been issued. What's the compliance impact on you?

To find out, dial in to discuss it with Stark law expert S. Craig Holden (Ober/Kaler, Baltimore, MD).

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