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Stark II Clarifications Bring Sweeping Changes to Recruiting and Referral

The long-awaited clarifications for Stark II have finally arrived, and many physician contracts, including those already in effect, will have to be reviewed. In a number of cases, contract clauses with groups and hospitals need to be removed or revised by July 26 of this year to comply with the changes in the regulations. In other situations, previously prohibited transactions and recruitment arrangements will now be allowed.

The US Department of Health and Human Services published the interim final rule in the *Federal Register* on March 26, 2004 (a corrected version was published on April 6, 2004, pages 17933-17935) and accepted comments through June 2004. Penalties for noncompliance include civil penalties

of up to \$100,000 for each intentional violation as well as withheld reimbursement payments and government paybacks. "It is important to begin reviewing contracts and employment relationships now because the interim final rule is effective July 26, 2004," says Ellen Luepke, Esq., a health care attorney at Barnes & Thornburg, LLP, located in Chicago.

Stark reality

The new clarifications cover a wide range of practice issues, from physician charity donations to business relationships with family members who practice medicine. The changes were developed by the Centers for Medicare & Medicaid Services (CMS) in an effort to reduce the regulatory burden, and in general, the new rules provide additional clarity and flexibility, observes Luepke.

When it comes to recruitment and physician contracts, however, there are two major clarifications that must be addressed soon. "First, the only costs to the physicians' group that can be picked up by the hospital as part of the subsidy for recruitment are incremental costs," says Michael F. Anthony, Esq., who is in the Chicago office of the law firm McDermott, Will & Emery. These are costs to the group that would not otherwise be incurred without the new financial arrange-

ment. Allocations of fixed, existing costs that are already part of the group's cost structure cannot be covered by the hospital. "For example, if a physician group had a supporting employee before the recruitment, the hospital cannot cover the costs of that employee's salary," Anthony explains. "If the employee is newly hired to support the physician's practice, the hospital could include that salary as part of the subsidy calculation." The change requires that groups understand and review their incremental costs.

This clarification has caused concern, since it does not exempt previous contracts or grant a grace period. As it stands now, the clarification applies to contracts going back 36 months. "We hope that CMS considers a grandfather clause for previous contracts. If not, it will be of concern to many individuals who have to restructure contracts in order to meet the new regulations," says Jerry Weissman, vice president of medical staff development for Community Health Systems. The Brentwood, Tenn.-based health care system includes more than 70 hospitals in 22 states and has many physician recruitment agreements that will be affected directly by the change, he adds.

"Before these changes, recruitment agreements were not limited to these new arrangements," Weissman recalls.

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An Occasion for Cautious Optimism

A 2004 survey of physicians aged 50 to 65 years by Merritt, Hawkins and Associates, a Texas-based physician search and consulting firm, indicates that many participants have grown disenchanted with their work. Of 476 respondents, 76% said that in the last five years, they have found the practice of medicine less satisfying; 9% said it was more satisfying, and 15% said their level of satisfaction has remained the same. The single greatest source of satisfaction for 58% of participating physicians is patient relationships; in a distant second-place position is intellectual stimulation (21%). Only a minority said they primarily enjoy the prestige (4%) and the financial rewards (4%).

Among the biggest frustrations for those taking part in the survey: malpractice worries (28%), managed care (16%), Medicare and Medicaid regulations (13%), long hours (10%), and the pressures of running a business (10%). In fact, 45% said they spend seven or more hours a week on billing and coding, compliance, and other administrative duties. (The survey—and others—can be found at www.merritthawkins.com.)

Statistics like these suggest that the recently published Stark II physician self-referral regulations are likely to be perceived as another burden. While the final 551-page document makes for some heavy reading, it appears that the final rule actually makes it easier for certain business arrangements to qualify as compensation exceptions; simply put, they're allowable. It also details the rules for a number of previously ambiguous issues, such as professional courtesy; bona fide charitable donations by physicians to tax-exempt facilities; retention payments in underserved areas; referral of patients to general or specialty hospitals in which the treating physician has an investment interest; and provides final clarification regarding ownership of and compensation for designated health services. In addition, the rules provide a grace period for temporary noncompliance. Our cover article introduces aspects of this massive piece of legislation, and we will continue to explore it in future issues.

If you're in a rural area, you may have wondered whether or not you should seek rural health center status. This month, we help you make an informed decision. We also take a look at some of the new ICD-9-CM codes that go into effect in October. Make note of them now—the 90-day grace period no longer exists.



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This newsletter is published by Premier Healthcare Resource, Inc., Morristown, NJ.

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When It Makes Sense to Pursue a Rural Health Clinic Designation

A young obstetrician-gynecologist (OB-GYN) who was preparing to join a rural practice in the southeastern United States was puzzling over an issue important to many country doctors: Would the practice, which was owned by a very small hospital, qualify as a rural health clinic (RHC), and was seeking this status a worthwhile effort?

Questions like these are not unusual among physicians in sparsely populated parts of the nation, but overburdened practitioners may be put off by the prospect of a qualification process and different billing procedures. "Over the years, I've talked to clients that I know would qualify, but they just don't want to deal with it," says John W. McDaniel, president and CEO, of Peak Performance Physicians, LLC, which is based in New Orleans, La. "They're just leaving money on the table," adds Dennis Owens, president and CEO of Rural Health Associates, located in Wichita, Kansas. "I have a client who's been thinking about applying for RHC status for eight years."

Some physicians stall because they expect the program to be dismantled, though there is no evidence to support that position. The RHC program was established in 1977 to draw health care practitioners to underserved areas. Nearly 30 years later, about 25% of Americans are living in rural locales, and just 10% of physicians are practicing in them, according to the Rural Healthy People 2010 Project. "When you look at the political power in rural areas, I don't think many of us will live to see the program fade away," McDaniel says. Owens agrees, noting, "I think there will be changes through the years as there are with all government programs. But right now, politicians want

to deal with rural health issues."

Two key benefits

The main advantage of RHC status is more generous compensation for care given to patients covered by Medicare or Medicaid. In fact, if a practice has at least 50% of its total visits paid for by Medicare and Medicaid, overall annual revenues commonly climb by 25% to 75% once RHC certification is granted, according to *Starting A Rural Health Clinic—A How-To Manual*, published in 2004 by the Office of Rural Health Policy (see "For More Information," page 4).

Medicare bases reimbursement on the costs associated with providing services. If the clinic is owned by a hospital with 50 or fewer active beds, there is currently no upper limit on the payments the RHC receives. "I may have a visit that Medicare would normally pay \$40 for but under the cost basis, if I can show that it cost me \$100 to provide the relevant services, then Medicare will pay \$100 for the visit," Owens explains. The term "active beds" does not pertain to total capacity. A 100-bed hospital with an average occupancy of 30% would have fewer than 50 active beds.

RHCs owned by a hospital with more than 50 active beds receive a flat fee per visit for care given to patients covered by Medicare. Compensation is linked to the clinic's

yearly expenditures and is subject to a maximum payment—\$68.65 per visit for fiscal year 2004. The same is true of RHCs owned by physicians. Even with a capped flat fee, an RHC probably earns about \$15 more than a non-RHC office in the same state providing the same service to a Medicare patient, Owens estimates.

Generally, Medicaid is authorized to use a prospective payment system (PPS); that is, to pay a predetermined flat rate for each service rendered by an RHC. However, state Medicaid programs are allowed to construct their reimbursement methods differently, as long as they provide amounts comparable with what a PPS would afford. Again, RHCs are likely to receive at least \$15 more per visit than a conventional practice would get.

Another significant incentive allows care furnished by certified nurse midwives (CNMs), nurse practitioners (NPs), and physician assistants (PAs) to be reimbursed at the physician's rate, Owens notes. This is not incident-to-billing, which allows physicians to charge the midlevel practitioner's services at the physician's rate when the physician is on the premises at the time that treatment is supplied. In contrast, the RHC-based physician, though responsible for the quality of care afforded patients by midlevel providers, need only be available in

(Continued on page 4)

the clinic at least one day every two weeks, unless the state requires more frequent periods of direct supervision for its CNMs, NPs, or PAs.

Who is eligible?

Certification as an RHC demands that a practice be situated in a region that not only meets the Census Bureau's definition of rural—a non-urbanized location with a population of fewer than 50,000—but has also been identified within the previous three years as a health professional shortage area (HPSA) or a medically underserved area. Besides one or more physicians, the practice must have at least one CNM, NP, or PA who is treating patients on-site during at least half of the hours the office is open.

Aside from delivering outpatient primary care services, a potential RHC must be capable of performing six basic laboratory tests on the premises (chemical evaluation of urine; hemoglobin or hematocrit; blood glucose; examination of stool specimens for occult blood; pregnancy

tests; and primary culturing for transmittal) and providing emergency services. Written patient care policies must be prepared as well. Specialists are not included in the RHC program, although those who do treat patients within an HPSA should bill their services with a QB modifier to receive a 10% incentive payment.

Practices that meet the basic criteria file an application with the state agency charged with administering the RHC program for the Centers for Medicare and Medicaid Services. "They will then come out and survey the clinic to make sure it falls within the regulations; that safety and service requirements have been met; and all their policies and procedures are in order and documented," Owens explains. "If you pass the survey, you can file your initial cost report to illustrate what you think it's going to cost you to provide a service. That process used to take three to four months. Now it's taking anywhere from six months to one year. I think more people are applying, but I also think cost cutting

has left us with fewer surveyors."

Both McDaniel and Owens have an essential piece of advice for physicians considering RHC status: Make sure you will actually benefit from it. Consider the cost of hiring a midlevel practitioner, if you don't already have one. Remember that that employee must be in place before the site survey occurs. Figure out the patient volume you would need to justify the extra salary and set of benefits. Take a look at your coding profile to gauge what your payments are already averaging. Examine the percentage of patients enrolled in Medicare and Medicaid—at least 50% must be in one of these programs before you gain any advantage from RHC certification. If your practice is new, wait at least three to six months and then evaluate all of these factors so that you can make a more realistic assessment. "In the last 15 years, I've probably told about five clinics that they shouldn't apply for RHC status because their volume wasn't sufficient," notes Owens, who provides free feasibility studies to physicians contemplating an application.

As for the OB-GYN signing on with the rural hospital-owned practice: he was advised to put off a decision for several months. The clinic is fairly new, and the population of Medicare patients is quite small, perhaps 3%. However, it's expected that Medicaid will cover 40% to 50% of patients. In the meantime, the hospital should treat the clinic like another hospital department, assigning it pertinent expenses and revenues, McDaniel suggests. "Waiting is a wise idea," Owens remarks. "You always want to make sure your foundation is solid before you venture out and try something new."

Reported and written by Cynthia Starr, editor. For more information on practicing in underserved areas, visit our Web site (see page 8).

For More Information

The following Web sites provide lots of good information on rural health:

Centers for Medicare and Medicaid Services
Rural Health Information Resource
www.cms.hhs.gov/providers/rh/

Health Resources and Services Administration, Office of Rural Health Policy
ruralhealth.hrsa.gov
Starting A Rural Health Clinic—A How-To Manual
ftp.hrsa.gov/ruralhealth/RHCmanual1.pdf

National Association of Rural Health Clinics
www.narhc.org

National Rural Health Association
www.nrharural.org

Rural Healthy People 2010 Project
<http://www.srph.tamushsc.edu/rhp2010/>

Check Out New ICD-9-CM Codes Before You Need to Use Them

Come October 1, 2004, the new and newly modified ICD-9-CM codes will only be available in an immediate-release form. That is, now that the Centers for Medicare and Medicaid Services (CMS) has done away with its traditional 90-day grace period, physicians need to begin using the latest codes the day they go into effect. Claims carrying discontinued codes for services provided on or after October 1 will be denied. The CMS notes that institutional providers have never had a grace period.

With this in mind, you should examine the most recent batch of ICD-9-CM codes. As always, the new codes aim for improved specificity. For example, code 707.0, decubitus ulcer, is to be replaced by nine new codes, including seven that indicate a location. Coding changes also reflect what's going on in medicine, such as advances in knowledge and technology. Five new V codes describe genetic susceptibility to cancer: V84.01, genetic susceptibility to malignant neoplasm of breast; V84.02, genetic susceptibility to malignant neoplasm of ovary; V84.03, genetic susceptibility to malignant neoplasm of prostate; V84.04, genetic susceptibility to malignant neoplasm of endometrium; and V84.09, genetic susceptibility to other malignant neoplasm. Code 066.4, adopted two years ago to designate West Nile Fever, will be exchanged for four codes with more clear-cut descriptions. Four other new codes, 629.20 through 629.23, denote female genital mutilation.

Dozens of diagnosis code titles have been modified. For example, the fifth-digit subclassifications for diabetes mellitus (DM) will no longer include

the following terms: insulin dependent type (IDDM), non-insulin dependent type (NIDDM), or adult-onset type. Instead DM, whether uncomplicated or associated with other disorders, will be described in a fifth digit as stemming from type II or unspecified type, not stated as uncontrolled (0); type I [juvenile type], not stated as uncontrolled (1); type II or unspecified type, uncontrolled (2); and type I [juvenile type],

uncontrolled (3). Many psychiatric code titles have been revised as well.

A sampling of new codes appears in the accompanying table. The entire list can be found at the following Web sites: www.cms.hhs.gov/medlearn/icd9code.asp or www.cdc.gov/nchs/icd9.htm.

Reported and written by Cynthia Starr, editor. More information on coding is available on our Web site (see page 8).

Selected New ICD-9-CM Codes

Code	Description
070.70	Unspecified viral hepatitis C without hepatic coma
070.71	Unspecified viral hepatitis C with hepatic coma
252.01	Primary hyperparathyroidism
252.02	Secondary hyperparathyroidism, non-renal
273.4	Alpha-1-antitrypsin deficiency
277.85	Disorders of fatty acid oxidation
347.10	Narcolepsy in conditions classified elsewhere, without cataplexy
347.11	Narcolepsy in conditions classified elsewhere, with cataplexy
380.03	Chondritis of pinna
453.40	Venous embolism and thrombosis of unspecified deep vessels of lower extremity
453.41	Venous embolism and thrombosis of deep vessels of proximal lower extremity
453.42	Venous embolism and thrombosis of deep vessels of distal lower extremity
477.2	Allergic rhinitis, due to animal (cat) (dog) hair and dander
491.22	Obstructive chronic bronchitis with acute bronchitis
622.10	Dysplasia of cervix, unspecified
622.11	Mild dysplasia of cervix
622.12	Moderate dysplasia of cervix
692.84	Contact dermatitis and other eczema due to animal (cat) (dog) dander
705.21	Primary focal hyperhidrosis
705.22	Secondary focal hyperhidrosis
780.58	Sleep-related movement disorder
788.38	Overflow incontinence
790.95	Elevated C-reactive protein (CRP)
V01.71	Contact or exposure to varicella
V01.79	Contact or exposure to other viral diseases
V01.83	Contact or exposure to escherichia coli
V01.84	Contact or exposure to meningococcus
V58.66	Longterm (current) use of aspirin
V58.67	Longterm (current) use of insulin
V69.4	Lack of adequate sleep
V72.31	Routine gynecological examination

“We use several national guidelines to determine the cost of bringing someone into a practice, then offer a contract arrangement in which a percentage of those costs is subsidized to the established practice. We required the practice to share some of the financial risk.” With the new requisites, though, contracts must incorporate specific incremental costs. “We will need to include an amendment to existing contracts to reflect the new requirement on incremental costs. We probably will also be devising new contracts that will comply with the new Stark II regulations.”

Restrictive covenants prohibited

The second primary clarification prohibits a physician's group or hospital from imposing a restrictive covenant on physicians in their employment contracts, says Anthony. Restrictive covenants are clauses stating that if the relationship with a physician is terminated, the departing physician cannot practice in the group's geographic area. “If there is a restrictive covenant in a physician's agreement with the group, group leaders and hospitals must sit down together and rework those employment contracts by July 26,” Anthony says.

“Most hospitals and groups are not yet focusing on the timetable because these changes were not anticipated,” he points out. Nonetheless, for any hospital and group that works together, remedial action should be a high priority.

The change will have a broad influence for many practitioners. “Our recruitment strategy is to establish that a community need exists and then to recruit physicians or assist established practices in those communities with a recruitment effort,” says Weissman. The practices could do the recruitment themselves,

without assistance from Community Health Systems, he notes, but they must now be aware that restrictive covenant clauses are forbidden.

Overall, Weissman believes the new regulations pertaining to incremental costs and restrictive covenants are probably necessary and may be helpful in the long run. “They mean that everyone will have to play by the same rules,” he remarks. “In the past, we would assist an established practice with a limited subsidy without explicit incremental expenses submitted, but now we will only be able to do that when these costs are provided because the rules are very specific.” But making the needed modifications will be a learning process for everyone involved. “There will be some concern if we need to go back over contracts that are not grandfathered, for whatever period of time is required,” he says. For now, Community Health Systems is pushing ahead, and hospitals in the system are being alerted about the changes. “We've told them to avoid providing misinformation to the doctors by waiting until the comment period is over before having specific conversations about the changes,” Weissman says.

Other revisions

Aside from recruiting arrangements, the interim final rule includes a wide range of other clarifications as well. Here are some highlights:

- Physicians and immediate family members can make charitable donations to tax-exempt organizations or facilities to which they refer if the donation is not solicited and if it does not take into account the volume or value of referrals. An example is a ticket to a hospital charity ball or a contribution to a charitable health care entity's general fund-raising campaign.

- Professional courtesy services (those provided free or at a discount to physicians, their families, and their staffs) are now allowed if the provider offers professional courtesy to all of the physician's medical staff members, regardless of referral patterns.
- Physicians can establish physician referral services.
- Physicians can receive assistance from recruiters to pay or help pay malpractice insurance premiums.
- Entities can provide a physician or a group practice with new information systems or components that allow them to participate in community-wide health information systems.
- Physicians in rural areas can refer their patients to other physicians in their family.
- Self-referrals for certain specialty groups that provide oncology and radiology services are allowed.
- Self-referrals for preventive screening tests and immunizations that are reimbursed by Medicare are allowed.
- End-stage renal disease facilities can provide a bigger selection of dialysis-related prescription drugs to patients undergoing treatment without violating self-referral rules.
- A 90-day grace period is provided when persons are noncompliant with a Stark exception. This applies only when the noncompliance is traceable to events outside of the person's control or the person is temporarily unable to comply.
- Clarifications were also included for many of the defined terms of the Stark law.

Generally, the clarifications give physicians more flexibility in how their arrangements can be devised. One definition refined in the clarifications is that of an indirect financial

A Work in Progress

The Stark law has had a long and complex history. Beginning with the 1989 Ethics in Patient Referral Act, also known as Stark I, the initial legislation only prohibited physician referrals to clinical laboratories in which the physician has a financial interest. The Omnibus Budget and Reconciliation Act of 1993 expanded the law to prohibit referrals to additional designated health services (DHS). Known as Stark II, this expansion further banned self-referral for physical, occupational, and speech therapy services, as well as radiology, imaging, and radiation services, durable medical equipment supplies, home health services, outpatient prescription drugs, hospital services, parenteral and enteral nutrients and supplies, and prosthetics. (The latest ruling allows physicians to provide canes, crutches, wheelchairs, walkers, and blood glucose monitors to patients in their practices if certain conditions are met, however.) The 1993 law stated that an entity receiving a prohibited referral could not present a claim to Medicare or another third-party payer for reimbursement of the services.

In 2001, a final rule for the law established two main exceptions to Stark II. Under these exceptions, physicians could refer patients to other physicians in their group practice as well as to certain ancillary DHS within their own practices, if several conditions of location, supervision, and billing were met.

Because the 2001 final rule was still vague in a number of areas, though, further clarifications were needed, and Phase I of the clarifications was issued in January 2002. Phase II of the clarifications consists of the interim final rule that was published in the *Federal Register* on March 26, 2004, and it takes effect on July 26, 2004. Phase III for the final regulation is still to come and will mainly clarify how the Stark law applies to Medicaid.

relationship. Under this new exception, an indirect compensation agreement between a physician and another entity is not considered a financial relationship under Stark if the compensation to the physician is of a fair market value for the services provided and does not take into account the value or volume of referrals and if the agreement is in writing. The agreement cannot violate federal anti-kickback law, however.

The in-office ancillary exception was also broadened and expands the criteria for qualification as a group practice. Physician supervision requirements were also eased considerably as were the definitions of referrals. Finally, the definition of 'volume or value' was also clarified.

Compensation changes

The interim final rule also made alterations in the regulations for certain physician compensation arrangements. Specifically, the final rule now protects compensation between a physician and an entity providing a designated health service when there is a written agreement that describes the services and the time frame for the arrangement. The compensation must reflect fair market value, however, and needs to be divorced from the volume or value of referrals. Such compensations can be provided even when the exact dollar amount cannot be initially determined, as long as the parties agree to the formula for calculating the compensation and the physician person-

ally performs the services. The recent changes thus protect previously endangered percentage-based payments and per-unit-of-service compensation arrangements between physicians and entities to which they may refer.

Other compensation changes include:

- Hospitals can make payments to induce physicians to continue practicing in their community if their services are needed, but only if the physician has received an offer from another hospital.
- Nonmonetary compensation worth up to \$300 per year to physicians is allowed if the doctor did not solicit the compensation and if the dollar amount is not determined by the volume or value of referrals.
- Compensation given to a physician as part of a risk-sharing arrangement, including bonuses and withholds, is not in violation of Stark.
- Physician training provided by a hospital is allowed if the training is held in the community or service area.

Because the interim final rule becomes effective in July 2004 it is crucial for physicians and recruiters to ensure that their contracts and agreements are in compliance with the new clarifications without delay. Specifically, reviews should be done to determine whether previously prohibited arrangements might now be allowed under Stark II and whether arrangements that were once legal are now prohibited.

To see the interim Final Rule, go to: www.access.gpo.gov/su_docs/fedreg/a040326c.html.

Reported and written by Deborah Epstein, contributing editor in West Milford, N.J. More information on the Stark legislation is available on our Web site (see page 8).

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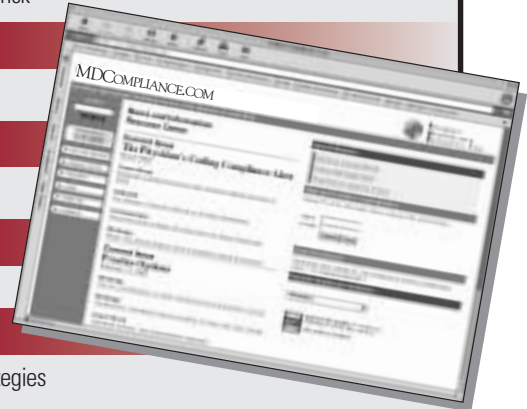
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