

rehabilitation agency definition requiring a rehabilitation agency provide social or vocational services. We are also proposing to make a conforming change at 485.717.

At 485.711(b)(3), we are proposing to remove the reference to §410.61(e), since §410.61(e) no longer exists in regulation.

M. Technical Corrections for Therapy-Related Issues

[If you choose to comment on issues in this section, please include the caption "THERAPY-RELATED ISSUES" at the beginning of your comments.]

We are proposing the following technical changes to the regulations concerning therapy services:

- In §409.17(a), we are proposing to delete the reference to paragraph (a)(1)(ii) which no longer exists.
- In §409.23, we are proposing to revise the title of this section from "Physical, occupational and speech therapy" to "Physical therapy, occupational therapy and speech-language pathology services."

N. Physician Self-referral and Anti-markup Issues

[If you choose to comment on issues in this section, please include the caption "PHYSICIAN SELF-REFERRAL AND ANTI-MARKUP ISSUES" at the beginning of your comments.]

1. Changes to Reassignment Rules Related to Diagnostic Tests (Anti-Markup Provision)

a. CY 2008 PFS Final Rule with Comment Period

The CY 2008 PFS final rule with comment period (72 FR 66222) amended the anti-markup provision in §414.50 for certain diagnostic tests. We revised the anti-markup provision to apply to the technical component (TC) of diagnostic tests that are ordered by the billing physician or other supplier (or ordered by a party related by common ownership or control to such physician or other supplier), when the TC is outright purchased or when the TC is not performed in the office of the billing physician or other supplier. We also imposed an anti-markup provision on the professional component (PC) of diagnostic tests that are ordered by the billing physician or other supplier (or ordered by a party related by common ownership or control to such physician or other supplier group), if the PC is outright purchased or if the PC is not performed in the office of the billing physician or other supplier. The anti-markup provision in §414.50 applies to the TCs and PCs of diagnostic tests covered under section 1861(s)(3) of the Act and paid for under 42 CFR part 414 (other than clinical diagnostic laboratory tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special billing rules set forth in section 1833(h)(5)(A) of the Act). If a physician or other supplier bills for the TC or

PC of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such physician or other supplier through common ownership or control) and the diagnostic test is either purchased from an outside supplier or performed at a site other than the office of the billing physician or other supplier, the payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by the beneficiary or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

- The performing supplier's net charge to the billing physician or other supplier.
- The billing physician or other supplier's actual charge, or
- The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

In revised §414.50(a)(2)(iii), we defined the "office of the billing physician or other supplier" as medical office space where the physician or other supplier regularly furnishes patient care. For a billing physician or other supplier that is a physician organization (as defined at §411.351 of this chapter), the "office of the billing physician or other supplier" is space in which the

physician organization provides substantially the full range of patient care services that the physician organization provides generally. (For purposes of the anti-markup provision, the office of a billing physician or other supplier has its common meaning - that is, it is space in which the physician or other supplier regularly furnishes patient care services, and does not include a "centralized building" as defined at §411.351).

We effectuated our changes primarily by modifying §414.50, although we also modified §424.80 by adding paragraph (d)(3) to alert the reader that, in a case of the reassignment of the TC and/or PC of a diagnostic test, the reader should consult §414.50 to investigate whether the anti-markup provision applies to the TC and/or PC. We also amended the definition of "entity" at §411.351 to exclude a physician's practice when it bills Medicare for the PC of a diagnostic test in accordance with §414.50. (Prior to the CY 2008 PFS final rule with comment period, the definition of "entity" at §411.351 excluded a physician's practice when it bills Medicare for the TC of a diagnostic test in accordance with §414.50.)

b. Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-

Markup Provision for Certain Services Furnished in Certain Locations (§414.50) Final Rule (73 FR 404)

Subsequent to the publication of the CY 2008 PFS final rule with comment period (72 FR 66222), we received informal comments from various stakeholders that stated that the application of the rule was unclear with respect to whether certain types of space arrangements meet the definition of the "office of the billing physician or other supplier." Further, some of these stakeholders stated that patient access may be significantly disrupted due to the alleged inability of physician groups to render services in a cost-effective manner if medical office space that satisfies the "same building" test in §411.355(b)(2)(i) of this chapter for purposes of the physician self-referral rules in Part 411, Subpart J of this chapter, and other medical office space in which patients are seen and that complies with the physician self-referral rules, are subject to the anti-markup provision in revised §414.50. That is, physician groups stated that, in situations in which they are subject to the anti-markup provision and are limited to billing Medicare the net charge imposed by the performing supplier, they will not be able to continue to provide diagnostic testing services to the same extent that

they are currently providing such services, because they will not be able to recoup their overhead costs.

We were concerned that the definition of "office of the billing physician or other supplier" may not have been entirely clear and that it could have unintended consequences. Accordingly, in order for us to study the issues further, we issued a final rule entitled "Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Delay of the Date of Applicability of the Revised Anti-Markup Provisions for Certain Services Furnished in Certain Locations (§414.50)" (the "Delay Rule"), which delayed, until January 1, 2009, the applicability of the revised anti-markup provision in §414.50, except for anatomic pathology diagnostic testing services furnished in space that: (1) is utilized by a physician group practice as a "centralized building" for purposes of complying with the physician self-referral rules; and (2) does not qualify as a "same building" under §411.355(b)(2)(i) (73 FR 404). We stated that, during this period, we planned to issue clarifying guidance as to what constitutes the "office of the billing physician or other supplier" or propose additional rulemaking, or both. Because anatomic pathology diagnostic testing arrangements precipitated our proposal for revision

of the anti-markup provision and remained our core concern, we did not delay the date of applicability with respect to anatomic pathology diagnostic testing services furnished in certain space (as described above). In addition, we did not delay the applicability of the revised anti-markup rule for the TC of any purchased diagnostic test. The anti-markup prohibition for the TC of purchased diagnostic tests is longstanding and was incorporated into the expanded and revised provisions of §414.50. Accordingly, the regulation remained applicable to the TC of any purchased diagnostic test.

c. Challenge to the CY 2008 PFS Final Rule with Comment Period and the Subsequent Delay of the Date of Applicability Final Rule

On January 25, 2008, a group of plaintiffs filed suit against the Secretary (Atlantic Urological Associates PA v. Leavitt, Civil Action No. 08-141-(RMC) (D.D.C.)), challenging the validity of the CY 2008 PFS final rule with comment period and the subsequent Delay Rule, and asking the Court to enjoin the application of the CY 2008 PFS final rule with comment period as to them. The plaintiffs included the following: (1) three urology physician group practices that own pathology laboratories; (2) a self-employed pathologist who performs testing services for

other physician groups; (3) Uropath, LLC, a limited liability company that manages various pathology laboratories; and (4) Uropath's Director of Clinical Operations. The Secretary moved to dismiss the complaint for lack of standing and lack of jurisdiction. The Secretary agreed to withhold implementation of the anti-markup rule, as amended by the Delay Rule, for claims submitted between February 1, 2008 and April 1, 2008, so that the parties could fully brief the issues. Subsequently, a preliminary injunction was granted by the Court until the date of its final order.

On May 5, 2008, the Court vacated the preliminary injunction order and granted the Secretary's motion to dismiss the suit. The Court found that the plaintiffs did not have standing to challenge the delay of the applicability of the anti-markup provisions for some arrangements. The Court further found that Uropath and its Director of Clinical Operations lacked standing to challenge either the CY 2008 PFS final rule with comment period or the subsequent Delay Rule due to the fact that they are not Medicare providers or suppliers and, thus, had no legally protected interest at stake. Finally, the Court found that, even if the plaintiffs had standing, the physician groups and the self-employed pathologist must

exhaust the administrative claims process before the matter could be heard in Federal court.

d. Specific Proposals

As finalized in the CY 2008 PFS final rule with comment period, the anti-markup provision applies to the TCs or PCs of diagnostic tests that are either purchased from an outside supplier or are performed outside of the "office of the billing physician or other supplier."

Here, we are proposing two alternative approaches for revising the anti-markup provision in §414.50. In addition, we are seeking comments regarding any other possible approaches that would address our concerns regarding overutilization motivated by the ability of a physician or physician organization to profit from diagnostic testing services not actually performed by or supervised by a physician who should be considered to "share a practice" with the billing physician or other supplier.

Under our first proposal, the anti-markup provision in §414.50 would apply in all cases where the PC or TC of a diagnostic testing service is either: (i) purchased from an outside supplier or (ii) performed or supervised by a physician who does not share a practice with the billing physician or physician organization (as defined at

§411.351). We would specify that a physician who is employed by or contracts with a single physician or physician organization shares a practice with that physician or physician organization. We believe that when a physician provides his or her efforts for a single physician organization (whether those efforts are full-time or part-time), he or she has a sufficient nexus with that practice to justify not applying the anti-markup provision as contemplated under section 1842(n)(1) of the Act. Under this proposal, a physician who is an employee of, or independent contractor with, more than one billing physician or physician organization would not "share a practice" for purposes of §414.50 with any of the physicians or physician organizations with which he or she is affiliated.

We believe that this proposal offers a simpler, more bright-line approach preventing potentially abusive arrangements while preserving the viability of nonabusive arrangements involving diagnostic testing facilities that might not be considered to be in the "office of the billing physician or other supplier," as defined under the current regulation (for example, a centralized laboratory staffed with full-time employees that is used by a physician practice with multiple office locations, sometimes referred

to as a "hub and spoke" arrangement). We are not proposing regulation text for this proposal.

We recognize that circumstances may exist under which it is beneficial, if not necessary, for a physician to provide diagnostic testing services to more than one physician practice. For example, a physician in one practice may contract to provide physician services on a locum tenens basis to another practice while a physician in that practice is on vacation or maternity leave. We are interested in comments regarding whether and, if so, how we could permit a physician to provide occasional services outside of his or her physician organization without that the secondary arrangement precluding the physician from "sharing a practice" with his or her physician organization for purposes of applying the anti-markup provision. We note that we do not consider providing services at a free clinic or moonlighting in a hospital emergency department or as a hospitalist to be "sharing a practice." Such activity would not require the application of the anti-markup provisions with respect to the services the physician provides for his or her physician organization.

Alternatively, we propose to maintain much of the current regulation text and its "site-of-service" approach to determine whether a physician "shares a practice" with

the billing physician or other supplier. In other words, we are re-proposing to apply the anti-markup provision to TCs and PCs of non-purchased tests that are performed outside the "office of the billing physician or other supplier". We are soliciting comments on whether this is the best approach or whether we should employ a different approach. As discussed in more detail below in this section, we are also proposing to amend §414.50 to: (1) clarify that the "office of the billing physician or other supplier" includes space in which diagnostic testing is performed that is located in the same building in which the billing physician or other supplier regularly furnishes patient care (and to make two other revisions to the definition); (2) clarify that, with respect to TCs, the anti-markup provision applies if the TC is either conducted or supervised outside of the office of the billing physician or other supplier; (3) clarify that a TC of a diagnostic test is not purchased from an outside supplier if the TC is supervised by a physician located in the office of the billing physician or other supplier; (4) clarify that, for purposes of applying the payment limitation in §414.50(a)(1)(i) only, the "performing supplier" with respect to the TC is the physician who supervised the TC and, with respect to the PC, the "performing supplier" is

the physician who performed the PC; (5) propose an exception for diagnostic tests ordered by a physician in a physician organization (as defined at §411.351) that does not have any owners who have the right to receive profit distributions; and (6) solicit comments on how to define "net charge" and on whether we should delay beyond January 1, 2009 the application of the revisions made by the CY 2008 PFS final rule with comment period, or the proposed revisions (to the extent they are finalized), or both.

i. Definition of the "Office of the Billing Physician or Other Supplier"

We received informal comments from various stakeholders who alleged that the application of the CY 2008 PFS final rule with comment period was unclear with respect to whether certain types of space arrangements meet the definition of the "office of the billing physician or other supplier." In addition, some of these stakeholders stated that patient access may be significantly disrupted due to the alleged inability of physician groups to render services in a cost-effective manner if the anti-markup provision applies to arrangements in which diagnostic testing services are performed in the same building as, but in space separate from, where patients are seen.

Stakeholders pointed to arrangements in which the office where a physician group sees patients is located on, for example, the third floor of a medical arts building, but the diagnostic imaging services are housed, for example, in the basement of the building. Stakeholders also cited arrangements in which two or more group practices in the same building may share a lab or other diagnostic testing facility in that building.

After further review, we are proposing to clarify the definition of "the office of the billing physician or supplier" in §414.50(a)(2)(iv) to include space, in which diagnostic testing services are performed, that is in the "same building," (as defined at §411.351), as where the ordering physician or other ordering supplier regularly furnishes patient care (and more specifically, for physician organizations, in the same building as where the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally). Note that the definition of "same building" at §411.351 specifically excludes a "mobile vehicle, van, or trailer". Therefore, diagnostic services provided in the parking lot of a building in which a physician group sees patients would be subject to the anti-markup provisions.

We are soliciting comments that describe current business arrangements (such as those that take place on a "campus") and that suggest any additional or alternative criteria that would permit such arrangements to avoid application of the anti-markup provision while addressing our concerns for the potential for overutilization.

We have received questions as to whether, for purposes of the definition of the "office of the billing physician or other supplier" a physician or other supplier may have more than one location at which it regularly furnishes patient care. We propose to clarify in §414.50(a)(2)(iv) that it may. In addition, some stakeholders responded to the requirement that, with respect to a billing physician or other supplier that is a "physician organization", the "office of the billing physician or other supplier" is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally. According to the stakeholders, a physician organization, such as a multi-specialty physician group, may not provide substantially its full range of services at any one location, but rather may provide substantially the full range of services for a certain specialty in one location, substantially the full range of services for a second

specialty in a second location, and so forth. In order to address this difficulty for physician organizations, we are proposing to revise §414.50(a)(2)(iv) to read "with respect to a billing physician or other supplier that is a physician organization (as defined at §411.351 of this chapter), the "office of the billing physician or other supplier" is medical office space where the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally.

Examples of Application of Our Proposed Definition of the "Office of the Billing Physician or Other Supplier".

We are providing the following examples in order to illustrate the effect of our proposals. For purposes of the following examples, assume that neither the TC nor the PC is purchased from an outside supplier.

Example 1. A physician group practice treats patients in space located on one floor of a building, and, in that space, provides substantially the full range of services that it provides generally. The group practice conducts diagnostic testing on another floor of the same building. The anti-markup would not apply because the office of the billing physician or other supplier includes the space on both floors.

Example 2. One or more physician group practices share space that is used for diagnostic testing and is located in the same building in which the group practices have their respective offices for seeing patients (and within those offices each group practice provides substantially the full range of patient care services that it provides generally). Again, the anti-markup provision would not apply because the office of the billing physician or other supplier (with respect to each group practice) includes the space on both floors.

Example 3. A group practice treats patients in Buildings A, B and C. In each of its offices in Buildings A and B, the group practice provides substantially the full range of patient care services that it provides generally, but that is not true for space located in Building C. The group practice provides diagnostic testing services in Buildings B and C. If we finalize the definition of the "office of the billing physician or other supplier" to include space in which diagnostic testing is performed that is located in the same building as where the ordering physician or other ordering supplier regularly furnishes patient care, the anti-markup provision would not apply to the diagnostic testing performed in Building B but would apply to the diagnostic testing performed in Building C.

We recognize that, unlike the first alternative proposal described above, our second alternative proposal may adversely affect certain "hub and spoke" and similar diagnostic testing services arrangements (see description above) in which a physician providing services in a centralized diagnostic testing facility owned by and serving a multi-site group practice has a significant nexus to the physician organization that employs or contracts with the physician. Therefore, we are proposing to provide an exception in §414.50(b) to the anti-markup provision that would be applicable to diagnostic tests ordered by a physician in a physician organization that does not have any owners who have the right to receive profit distributions. The exception would not apply to TCs purchased from an outside supplier, in recognition of the statutory command in section 1842(n)(1) of the Act and our longstanding rule. We are seeking comments as to whether the exception is sufficient to address any potential impediments to nonabusive "hub and spoke" arrangements caused by this second alternative approach, whether the exception is too narrow or too broad, and whether an exception to the application of the anti-markup rule under this second alternative approach is necessary at all.

ii. Performed at a Site Other Than the Office of the Billing Physician or Other Supplier

Section 414.50(a) provides that the anti-markup provision applies to the TC of a diagnostic test if the TC is performed outside of the office of the billing physician or other supplier. We propose to clarify that, if the TC is conducted outside of the office of the billing physician or other supplier, the anti-markup provision applies irrespective of whether the supervision takes place in the office of the billing physician or other supplier. We also propose to clarify that the anti-mark-up provision applies if the supervision of the TC takes place outside the office of the billing physician or other supplier, even if the TC is conducted in the office of the billing physician or other supplier. In other words, we would take the position that "performance" of the TC includes both the technician's work in conducting the test and the physician's supervision of the technician. Therefore, if either the conducting of the TC or the supervising of the TC takes place outside the office of the billing physician or other supplier, the anti-markup provision would apply.

iii. Outside Supplier

In the CY 2008 PFS final rule with comment period, we defined an outside supplier as "someone who is not an

employee of the billing physician or other supplier and who does not furnish the test or interpretation to the billing physician under a reassignment that meets the requirements of §424.80" (72 FR 66401). Subsequent to publication of the final rule with comment period, we received questions as to whether the TC of a diagnostic test would be purchased from an outside supplier if the technician conducting the TC is not an employee of the billing group but the physician supervising the technician is an employee or contractor of the billing group. We are proposing to provide in new §414.50(a)(2)(iii) that the TC of a diagnostic test is not purchased from an outside supplier if the TC is both conducted and supervised within the office of the billing physician or other supplier, and the supervising physician is an employee or independent contractor of the billing physician or other supplier. We believe that the presence of the technician and the supervising physician in the office of the billing physician or other supplier, and the fact that the supervising physician is an employee or independent contractor of the billing physician or other supplier may establish a sufficient nexus between the supervising physician and the billing physician or other supplier so as to constitute "sharing a practice" within the meaning of

section 1842(n)1) of the Act. We are providing proposed regulatory text in new §414.50(a)(2)(iii) for this proposal. We are also making two alternative proposals (each without proposed regulatory text). We propose, in the first alternative, that if the TC is conducted by a technician who is not an employee of the billing supplier, the TC is considered to be purchased from an outside supplier, regardless of where the technician conducts the TC and notwithstanding the employment status of the supervising physician and the fact that the test is supervised in the office of the billing physician or other supplier. As a second alternative, we propose that, where the TC is conducted by a non-employee of the billing physician or other supplier and outside the office of the billing physician or other supplier, the TC nevertheless will not be a purchased test if the supervising physician is an employee or independent contractor of the billing physician or other supplier and performs the supervision in the office of the billing physician or other supplier. We note that, if we were to adopt this second alternative, the TC would still be subject to the anti-markup provision under our proposal that the anti-markup provision applies if either the conducting of the TC or the supervising of the TC takes place outside the office of the billing

physician or other supplier, unless an exception applies (see section II.N.1.d.i. of this proposed rule).

iv. The Performing Supplier's Net Charge

Section 414.50(a)(1) provides that, where the anti-markup provision applies, Medicare payment to the billing physician or other supplier is limited to the lowest of three specified amounts, one of which, in §414.50(a)(1)(i), is "the performing supplier's net charge to the billing physician or other supplier." We have received comments concerning what the performing supplier's net charge would be in the situation in which a physician in a group practice supervises the performance of a TC but the group practice bills for the TC directly, that is, without a reassignment from the supervising physician. Stakeholders have questioned whether there are two suppliers, that is, the physician supervising the TC and the group practice billing for it, or whether there is only one supplier, that is, the group practice, given that the supervising physician is not effecting a reassignment.

We propose to clarify that for purposes of §414.50(a)(1)(i) only, the "performing supplier" of the TC is the physician who supervised the TC, and the "performing supplier" of the PC is the physician who performed the PC. Therefore, where the anti-markup provision applies, the

billing physician or other supplier would need to determine what it paid the physician for supervising the TC or for performing the PC.

v. Specific Solicitation of Comments

We are interested in receiving comments concerning the calculation of net charge for the PC when the anti-markup rules apply. In the CY 2008 PFS final rule with comment period, commenters objected that it would be difficult to calculate the net charge of the performing supplier. We stated that we did not believe that most suppliers would experience significant difficulty in calculating the net charge, despite the fact that some physicians are paid an aggregate monthly or annual amount for their services. In addition, we stated that suppliers could also choose to restructure their arrangements so that the anti-markup provision does not apply (72 FR 66318). Despite these responses in the final rule, we have received comments and questions concerning how to calculate the net charge. We are soliciting comments as to whether and how we should provide specific regulatory guidance for calculating the net charge.

Commenters specifically stated that our decision to exclude the overhead costs of the billing supplier in the net charge would have a detrimental financial impact upon

their practice and, ultimately, patient access to care. We are also soliciting comments on whether we should allow some overhead costs to be recovered by billing suppliers for services to which the anti-markup provision applies, and how our concerns about the potential for overutilization would be addressed if we were to allow some recovery of overhead.

We note that several States have enacted direct billing laws, under which physicians (primarily pathologists) are required to directly bill payors for their services and are prohibited from reassigning their right to payment to the ordering supplier. We are soliciting comments on whether, in addition to or in lieu of, the anti-markup provision, we should prohibit reassignment in certain situations and require the physician supervising the TC or performing the PC to bill Medicare directly.

Finally, we are soliciting comments on whether the revisions made by the CY 2008 PFS final rule with comment period should go into effect on January 1, 2009, as planned, and whether any proposals contained herein that may be finalized should go into effect on that date, or whether some or all of the revisions should be delayed past January 1, 2009.