

- For each compendium that we determine should be included on the list, the publisher or its designee must notify CMS, within 45 days from the publication date of each new edition or revision of the compendium, that a new edition or version is available. This will ensure that we have the most current information for each compendium. This may be provided electronically or via online access. We believe that this is necessary to permit us to efficiently ensure that the listed compendia continue to meet the conditions set forth in this rule.

- In addition to the annual process, we may generate a request for changes to the list of compendia at any time.

M. Physician Self-Referral Provisions

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

1. Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision)

Medicare rules currently prohibit the markup of the technical component of certain diagnostic tests that are performed by outside suppliers and billed to Medicare by a different individual or entity (\$414.50). In addition, Medicare program instructions restrict who may bill for the

professional component (the interpretation) of diagnostic test (CMS Pub. 100-04, Chapter 1, 30.2.9.1).

In the CY 2007 PFS proposed rule (71 FR 48982), we stated that recent changes to our rules on reassignment concerning the right to receive Medicare payment may have led to some confusion as to whether the anti-markup and purchased interpretation requirements apply to certain situations where a reassignment has occurred under a contractual arrangement. In addition, we expressed concern about the existence of certain arrangements that we believe are not within the intended purpose of the physician self-referral rules, which permit physician group practices to bill for certain services furnished by a contractor physician in a "centralized building." We also expressed concern that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic testing services and to then realize a profit when billing Medicare may lead to patient and program abuse in the form of overutilization of services and result in higher costs to the Medicare program (71 FR 49054).

In the CY 2007 PFS proposed rule (71 FR 48982), we proposed to amend \$424.80 to provide that if the TC of a diagnostic test (other than clinical diagnostic laboratory

tests paid under section 1833(a)(2)(D) of the Act, which are subject to the special rules set forth in section 1833(h)(5)(A) of the Act) is billed by a physician or medical group (the "billing entity") under a reassignment involving a contractual arrangement with a physician or other supplier who performs the service, the amount billed to Medicare by the billing entity, less the applicable deductibles and coinsurance, may not exceed the lowest of the following amounts:

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

We also proposed that, to bill for the TC, the billing entity would be required to perform the interpretation. In addition, we considered imposing certain conditions on when a physician or medical group can bill for a reassigned PC of a diagnostic test. We stated that we were considering the following conditions (which currently appear in manual provisions and are known as the purchased interpretation rules):

- The test must be ordered by a physician who is financially independent of the person or entity performing the test and also of the physician or medical group performing the interpretation.

- The physician or medical group performing the interpretation does not see the patient.

- The physician or medical group billing for the interpretation must have performed the TC of the test.

We stated that, although we welcomed comments on all aspects of our proposals, we were particularly interested in receiving comments on whether: diagnostic imaging tests should be excepted from any of our proposed provisions; the proposal in whole or in part should apply only to pathology services; any of the proposed provisions should apply to services performed on the premises of the billing entity and if so, how to define the premises appropriately. We also requested comments as to whether an anti-markup provision should apply to the reassignment of the PC of diagnostic tests performed under a contractual arrangement, and if so, how to determine the correct amount that should be billed to the Medicare program.

For our physician self-referral rules, we proposed to modify the definition of "centralized building" at §411.351 to require a centralized building to consist of at least

350 square feet. We further proposed that the proposed minimum square footage requirement would not apply to space owned or rented in a building in which no more than three group practices own or lease space in the "same building," as defined at §411.351 (that is, in a building with the same street address) and share the same "physician in the group practice" (as defined at §411.351). We also proposed that a centralized building must contain, on a permanent basis, the necessary equipment to perform substantially all of the designated health services (DHS) that are performed in the space in order to meet the definition of a centralized building. We solicited comments as to whether a centralized building should have a minimum square foot requirement, and if so, whether the minimum should be 350 square feet or an amount more or less than that. In addition, we sought comments regarding whether there should be an exception to any minimum square foot requirement, and if so, the circumstances under which an exception should apply.

For our proposal that the centralized building permanently contain the necessary equipment to perform substantially all of the DHS that is furnished in the centralized building, we sought comments on whether this test should be imposed, and whether at least 90 percent or

some other minimum percentage or measurement would be appropriate. We stated that we were also considering whether to require that, for space to qualify as a centralized building, the group practice must employ, in that space, a nonphysician employee or independent contractor who will perform services exclusively for the group for at least 35 hours per week. Finally, we sought comments on whether a group practice should be allowed to maintain a centralized building in a State different from the State(s) in which it has an office that meets the criteria in §411.355(b)(2)(i), and if so, whether space that is located in a different State must be within a certain number of miles from an office of the group practice that meets the criteria in §411.355(b)(2)(i) in order to qualify as a centralized building.

We received numerous comments on these proposals. As a result, we did not finalize our proposals in the CY 2007 PFS final rule with comment period. Based on the comments received and other information that we considered, we are proposing to impose an anti-markup provision on the TC and PC of diagnostic tests. We would apply the anti-markup provision irrespective of whether the billing physician or medical group outright purchases the PC or the TC, or whether the physician or other supplier performing the TC

or PC reassigns his or her right to bill to the billing physician or medical group (unless the performing supplier is a full-time employee of the billing entity). To prevent gaming, whereby the performing physician's or other supplier's net charge to the billing entity is inflated to cover the cost of equipment or space that is leased to the performing physician or other supplier, we would define "net charge" as exclusive of any amount that takes into consideration such charges. For example, consider the following hypothetical:

- The fee schedule amount for the PC of a particular diagnostic test is \$100.
- Performing Physician A rents office space and equipment from Group B for \$50 per test interpretation performed.
- Physician A charges Group B \$100 per test. In this example, pursuant to our proposal, Physician A's charge of \$100 would be deemed to take into account the \$50 rental fee imposed by Group B (simply by virtue of the rental arrangement). Therefore, Group B would not be allowed to bill the full fee schedule amount of \$100, but rather, would be limited to the lesser of Physician A's net charge determined exclusive of the amount that is deemed to have taken into consideration the lease expense, that is \$50, or

Group B's actual charge for the PC. We are also concerned that overutilization of diagnostic tests could continue despite our proposal to apply an anti-markup provision to TCs that are reassigned to, or outright purchased by, group practices. That is, our proposal in the CY 2007 PFS proposed rule to impose an anti-markup provision would not have addressed the situation in which the TC is performed by a part-time or leased employee of the group practice in a centralized building, and the group neither receives a reassignment from the employee technician (if the technician is not able to bill for the TC in his or her own right), nor purchases the TC outright from the technician. Therefore, we are proposing to apply an anti-markup provision to TCs that are performed in a centralized building, and are seeking comments on whether we should have such a provision and, if so, how we should effect such a provision (for example, through amending the definition of "centralized building" or through some other means. We would except the anti-markup provision for PCs ordered by independent laboratories because we do not believe that PCs ordered by independent laboratories pose a significant risk of program abuse because the independent lab is not ordering the TC. In States where the corporate practice of medicine doctrine is in effect, independent labs that are

organized as corporations are prevented from hiring physicians as employees to perform PCs of diagnostic tests.

In addition, we are proposing in §414.50 that--(1) the PC of a purchased test be subject to an anti-markup provision; (2) the anti-markup provision for the TC and PC apply to all arrangements not involving a reassignment from a full-time employee of the billing entity; (3) the performing physician's or other supplier's net charge be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or other supplier by the billing entity; and (4) the anti-markup provision not apply to independent labs that have not ordered the TC.

At this time, we are not proposing to make changes to the definition of "centralized building" (with the one possible exception noted below in this section). We believe that changes to the definition may be unnecessary in light of our proposals for an anti-markup provision on the TC and PC of diagnostic tests (although if we decide to impose an anti-markup for TCs performed by technicians in a centralized building, we may accomplish that through amending the definition of "centralized building"). If an anti-markup provision is finalized, we may evaluate at a later time whether to make any revisions to the definition

of "centralized building." We also are not proposing to adopt the purchased test interpretation rules in the context of reassignments because this provision may be unnecessary if we impose an anti-markup provision and because the purchased test interpretation rules may be problematic for multi-specialty group practices. Finally, in the CY 2007 PFS proposed rule, we proposed that, in order to bill for the TC of the diagnostic test, the billing physician or medical group must directly perform the PC. However, we believe this provision may be unnecessary if we impose an anti-markup provision and also would be problematic for independent labs that cannot employ physicians due to corporate practice of medicine restrictions.

2. Burden of Proof

We are proposing to add §411.353(g) to clarify that, consistent with our policy with respect to claims denials, in any appeal of a denial of payment for a DHS that was made on the basis that the service was furnished pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral. That is, the burden of proof is not on CMS or