

our contractors to establish that the service was furnished pursuant to a prohibited referral.

3. In-Office Ancillary Services Exception

One of the most important exceptions to the physician self-referral prohibition, applicable to services furnished by group practices and sole practitioners, is the in-office ancillary services exception. Section 1877(b)(2) of the Act sets forth an exception for certain services (other than durable medical equipment and parenteral and enteral nutrients) that are provided ancillary to medical services provided by a physician or group practice and that meet certain conditions. The in-office ancillary services exception is codified in §411.355(b).

Among other things, the exception allows patients of a sole practitioner or physician in a group practice to receive ancillary services in the same building in which the referring physician or his or her group practice furnishes medical services, including some services unrelated to the furnishing of DHS. The exception provides additional flexibility for patients seen by a physician in a group practice by allowing these patients to receive a test or procedure in another building in space owned or leased on a full-time, exclusive basis by a group practice (that is, a "centralized building" as defined at §411.351).

The in-office ancillary services exception does not contain certain requirements that are found in other compensation exceptions. For example, the exception for personal service arrangements in §411.357(d), like many of the compensation exceptions, requires that compensation be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. These requirements are not present in the in-office ancillary services exception. Also, under the "special rule for productivity bonuses and profit shares" in §411.352(i), a physician in a group practice may receive a share of profits or a productivity bonus for referred ancillary services, provided that the payment is not directly related to the volume or value of referrals.

We believe that the Congress included an exception for in-office ancillary services to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office. At the time of enactment, a typical in-office ancillary services arrangement might have involved a clinical laboratory owned by physicians located on one floor of a small medical office building. Under such an arrangement, a staff member would take a urine or

blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited.

However, services furnished today purportedly under the in-office ancillary services exception are often not as closely connected to the physician practice. For example, pathology services may be furnished in a building that is not physically close to any of the group practice's other offices, and the professional component of the pathology services may be furnished by contractor pathologists who have virtually no relationship with the group practice (in some cases, the technical component of the pathology services is furnished by laboratory technologists who are employed by an entity unrelated to the group practice). In other words, the core members of the group practice and their staff are never physically present in the contractor pathologist's office. Similarly, the contractor pathologists do not participate in any group practice activities; they attend no meetings (except for phone calls about individual patients), and do not obtain retirement or health benefits from the group practice. In sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS.

Even in the case of ancillary services furnished in the same building, there may be very little interaction between the physicians who treat patients and the staff that provide the ancillary services. For example, an entity with its own staff located in a large medical office building next to a hospital may furnish an array of diagnostic services, including clinical laboratory services and radiology services, to patients of physicians who practice in the building and own either the equipment or the entity.

Comments received on the Phase I and Phase II physician self-referral rules (66 FR 856 and 69 FR 16055, respectively) stated that the in-office ancillary services exception is susceptible to abuse. For example, in response to the 1998 physician self-referral proposed rule (66 FR 892), a commenter asserted that the Congress did not intend for a group practice to have multiple centralized office locations, except for the provision of clinical laboratory services. This sentiment was reiterated in response to the Phase I final rule when several commenters objected to the decision to allow group practices to have more than one centralized facility (69 FR 16075). In response to Phase II, we received hundreds of letters from physical therapists and occupational therapists stating

that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices. In addition, we have been informed by a number of physician specialists that the in-office ancillary services exception enables physicians to order and then subsequently perform ancillary services instead of making a referral to a specialist.

In the CY 2007 PFS proposed rule (71 FR 48982), we stated our intent to address certain types of potentially abusive arrangements in which group practice physicians make a referral for a DHS to a specialist who is an independent contractor of the group practice. The specialist then performs the service for the group practice in a "centralized building" and reassigns his or her right to Medicare payment to the group (which then bills Medicare at a profit).

Comments received on the CY 2007 PFS proposed rule stated that, although our proposal addressed potential abuses arising from referrals to independent contractors who perform services in a centralized building, it failed to address abusive arrangements within the physician's office. Our review of industry trade articles and discussions with trade associations has heightened our awareness of the proliferation of in-office laboratories

and the migration of sophisticated and expensive imaging or other equipment to physician offices. "Turn-key" operations, such as the arrangements described in this section for in-office laboratories and other ventures, are being marketed to physicians over the internet.

At this time, we decline to issue a specific proposal for amending the in-office ancillary services exception. Rather, we are soliciting comments as to whether changes are necessary and, if so, what changes should be made. We are interested in receiving comments on: (1) whether certain services should not qualify for the exception (for example, any therapy services that are not provided on an incident to basis, and services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, or complex laboratory services); (2) whether and, if so, how we should make changes to our definitions of same building and centralized building; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

4. Obstetrical Malpractice Insurance Subsidies