

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