

if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance.

In addition, we would include the requirement that the arrangement not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission (which is a requirement of our other compensation exceptions issued under our authority under section 1877(b)(4) of the Act).

#### 5. Unit-of-service (Per-Click) Payments in Space and Equipment Leases

Section 1877(e)(1) of the Act provides an exception to the prohibition of physician referrals for space and equipment leases, provided that certain requirements are met. Among the requirements, which are incorporated in our regulations in §411.357(a) and (b), are that the lease be commercially reasonable even if no referrals were made between the parties, and that the rental charges be set in advance, be consistent with market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. The statute also requires that the lease arrangement meet such other requirements as the Secretary may impose by regulation as needed to safeguard against program or patient abuse. We are concerned with

lease arrangements that are structured so that a physician is rewarded for each referral he or she makes for DHS. Such arrangements could take the form of a physician leasing equipment that he or she owns to a hospital, and receiving a per-use (per-click) fee each time a patient is referred by the physician-owner to the hospital for the use of the equipment. We are also concerned about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. For example, if a physician rents an MRI machine from a hospital only when the physician refers a patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital, the physician benefits financially and the arrangement could provide an incentive for overutilization or other program abuse.

In the 1998 proposed rule (63 FR 1714), we noted that we had been asked about situations in which a physician rents equipment (such as a magnetic resonance imaging (MRI) machine) to an entity that furnishes a DHS, such as a hospital, with the physician receiving rental payments on a per-click basis (that is, total rental payments increase each time the machine is used). We stated that we believed that this arrangement would not prohibit the physician from

otherwise referring to the entity, provided that these kinds of arrangements were typical and complied with the fair market value and other requirements included under the rental exception. However, we added that, because a physician's compensation under this exception may not reflect the volume or value of the physician's own referrals, the rental payments may not reflect per-click payments for patients who are referred for the service by the lessor physician.

In the Phase I rulemaking, we stated that we were substantially revising the proposed rule with respect to "the volume or value standard." We stated:

Most importantly, we are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals.  
(66 FR 876)

After reconsidering the issue, we are proposing that space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are

referred by a physician lessor to the entity. We believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee, and we would disallow such per-click payments, using our authority under section 1877(e)(1) of the Act, even if the statute does not expressly forbid per-click payments to a lessor for patient referred to the lessee.

Finally, we are soliciting comments on whether, using our authority under section 1877(e)(1) of the Act, we should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee, to the extent that such payments reflect services rendered to patients sent to the physician lessee by the entity lessor.

#### 6. Period of Disallowance for Noncompliant Financial Relationships

In response to the Phase II interim final rule with comment period (69 FR 16054), we received several comments that questioned what the period would be for which the physician could not refer DHS to the entity and the entity could not bill Medicare for the situation in which a financial arrangement between a referring physician and an entity failed to satisfy the requirements of an exception to the general prohibition on self-referrals.