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The New Provider-based Rules and Their Importance for Service Delivery Structure

ew rules, effective October 1, 2002, now govern the criteria and process for billing a health care service as "provider-based." The new federal provider-based entity regulations substantially impact both reimbursement levels and advisable business structures for furnishing health care services within larger, more complex integrated delivery systems. 67 Fed. Reg. 49982, 50078-50096.

The fundamental change is that the rules no longer permit a hospital merely to choose to treat a department or other facility, such as an outlying clinic or adjacent surgery center, as part of the hospital for billing purposes. *See* 42 C.F.R. § 413.65(b). To ensure that such departments and facilities are integral and subordinate to the main provider, federal law now specifies criteria that a facility must meet before billing as provider-based.

ON-CAMPUS VERSUS OFF-CAMPUS DISTINCTION

The primary concept that flows through nearly all of the provider-based regulations is the distinction between on-campus and off-campus facilities. A facility is on-campus if it is located: (1) in the physical area immediately adjacent to the main buildings; (2) within 250 yards of the main buildings; or (3) in other areas determined by the Centers for Medicare and Medicaid Services ("CMS") Regional Office to be on-campus. 42 C.F.R. § 413.65(a)(2). If a facility meets none of these location criteria, it is considered off-campus.

CORE REQUIREMENTS APPLICABLE TO BOTH

To bill and properly receive reimbursement as provider-based, both on- and off-campus facilities must meet a core set of criteria. First, if applicable state law permits, the facility proposed to be treated as provider-based must be operated under the same state license as the main hospital. 42 C.F.R. § 413.65(d)(1).

Second, clinical services at the facility and the main provider must be integrated. A number of sub-criteria must be met to show clinical integration, including: (1) professional staff at the facility have privileges at the main provider; (2) the main provider maintains the same monitoring and oversight of the facility as it does of any other department; (3) the medical director of the facility maintains a reporting relationship to the CMO or similar official of the main provider with the same frequency, intensity, and level of accountability as exists between the CMO and the medical director of another department; (4) medical staff committees of the main provider are responsible for clinical care in the facility; (5) medical records of the facility are integrated with the medical records of the main provider; and (6) patients treated at the facility who require further care have access to all services of the main provider, and are referred when appropriate to the main provider. 42 C.F.R. § 413.65(d)(2).

Third, financial operations of the facility must be integrated with the main provider, as evidenced by shared income and expenses between the main provider and the facility, facility costs are reported in a cost center of the main provider, and the facility's financial condition is included in the main provider's trial balance.

42 C.F.R. § 413.65(d)(3).

And lastly, the facility must be held out to the public as part of the main provider, so that patients entering the facility know they are entering the main provider and are billed accordingly. 42 C.F.R. § 413.65(d)(4).

ADDITIONAL REQUIREMENTS FOR OFF-CAMPUS FACILITIES

For on-campus facilities, the core requirements regarding licensure, clinical and financial integration, and public awareness are all that is required. For off-campus facilities, three additional criteria apply. First, off-campus facilities must be operated under the ownership and control of the main provider, which includes requirements that the main provider have final responsibility for administrative decisions, approval of contracts, personnel actions and policies, and medical staff appointments. 42 C.F.R. § 413.65(e)(1).

Second, off-campus facilities must be operated with the same level of reporting with the main provider as exists with one of the main provider's existing departments, and must integrate the following functions with the main provider: (1) billing; (2) records; (3) human resources; (4) payroll; (5) employee benefit package; (6) salary structure; and (7) purchasing. 42 C.F.R. § 413.65(e)(2)(iii).

Third, off-campus facilities in most cases must be located within a 35-mile radius of the main provider. 42 C.F.R. § 413.65(e)(3).

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JOINT VENTURES MUST BE ON-CAMPUS FACILITIES

Beyond the set of applicable criteria discussed above, the off-campus versus on-campus distinction dictates to what extent a provider may own or operate a facility with others (such as a physician group or another hospital) and bill for services at that facility as provider-based.

For instance, facilities operated as joint ventures may only be providerbased if they are located on the campus of one of the parties to the joint venture. 42 C.F.R. § 413.65(f)(2). If two hospitals enter into a joint venture to build or purchase a facility that is not located on the campus of either hospital, that facility may bill only as a freestanding facility. Moreover, all the other on-campus requirements described above apply to joint ventures. If the facility is on the campus of one joint venturer, the facility must be integrated adequately with the on-campus provider and held out to the public as an integral part of that provider, even though it is jointly owned or operated.

MANAGING OFF-CAMPUS FACILITIES AS PROVIDER-BASED

Off-campus facilities operated under management contracts must meet additional criteria to bill as provider-based. 42 C.F.R. § 413.65(h). The provider, not the management company, must employ all direct patient care staff, other than physicians, nurse practitioners, and other non-physician practitioners who are paid under the Medicare physician fee schedule. The facility must be integrated administratively with the main provider, and the main provider must have significant control over the operations of the facility. Lastly, the management contract must be held by the main provider itself, not by a parent organization. This last requirement ignores the reality that many providers often are not themselves separate legal entities with enforceable contract rights, but it points to the need for careful structuring of these management relationships. Id. None of these requirements apply to on-campus facilities operated under management contracts.

ATTESTATION PROCESS AND GRANDFATHERING: A COMPLIANCE ISSUE

Providers may request an advance determination from CMS that a facility is provider-based; but, generally, they are not obligated to make such a request. The important exception to this general rule is an off-campus physician clinic. These clinics are presumed free-standing unless a CMS provider-based determination is made. *See* 42 C.F.R. § 413.65(b)(4).

If a provider does not obtain a provider-based determination and CMS later finds that the facility does not meet the applicable criteria, CMS will recover the difference between the payment made for services performed at the facility and the payments that would have been made if the facility had billed as freestanding. 42 C.F.R. § 413.65(j).

The potential for large overpayment liability is a primary reason why compliance departments have an interest and likely a responsibility to oversee provider-based billing. In addition, billing with an incorrect site of service at provider-based facilities or violating the anti-dumping rules can result in revocation of provider-based status. *See* 42 C.F.R. § 413.65(g). These factors make clear the compliance and risk management side of the provider-based rules.

Whether a provider should obtain a CMS advance determination regarding provider-based status for an individual facility will depend to some extent on particular circumstances. But there are at least a few advisable guidelines: (1) advance determinations are appropriate for off-campus facilities in almost all cases; (2) an advance determination likely is not needed for ancillary departments within the hospital that are treated just like all other departments; and (3) any facility operated as a joint venture or under a management contract should obtain an advance determination.

For many facilities that have a long history of billing provider-based, the rules furnish a grandfathering period. Any facility that was treated as provider-based on October 1, 2000 has until the date of its first cost-reporting period beginning after July 1, 2003 to comply with the criteria in the new rules. 42 C.F.R. § 413.65(b)(2). This provision offers long-treated provider-based facilities a number of months to

implement any operational changes required under the new rules to retain provider-based status.

IMPACT OF NEW PROVIDER-BASED RULES

Many hospital administrators and operations and financial officers may not fully realize how broadly the new providerbased rules apply, or how their application can lead to startling results. Any ancillary department of the hospital, even areas located within the four walls of the main hospital facility, are subject to the providerbased rules. See 67 Fed. Reg. at 50081. This means that any department within a hospital building may suddenly become a freestanding facility if the providerbased criteria on clinical and financial integration are not met. For instance, hospital departments within the primary hospital building that are structured with less clinical oversight than other departments raise interesting and unsettled questions under the new rules. It is imperative that operational changes to ancillary departments be analyzed under the provider-based rules to ensure that the operational changes do not result unintentionally in inappropriate billing.

For hospitals seeking imaginative and resourceful service delivery models, whether by themselves or through joint ventures with other hospitals or physician groups, the provider-based rules present many challenges and some opportunities. The reimbursement differential between freestanding and provider-based facilities can be substantial and highly relevant to management decisions for structuring service models. The provider-based rules must be added to the other considerations regarding operational, financial and legal structure when contemplating how best to organize service delivery.

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