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PROVIDER -BASED VERSUS FREESTANDING? NEW RULES MAKE PROMPT COMPLIANCE IMPERATIVE

BY CARY M. ADAMS & ANTHONY M. PEREZ

The following article was prepared for the Northern California Chapter of HFMA. It will be published in two parts in the July and August 2000 issues of the chapter's on-line newsletter, Over The Edge Brief.

Many hospitals also operate other provider-based facilities and departments, such as skilled nursing facilities, home health agencies, or various outpatient clinics. Whether such facilities are considered provider-based or freestanding may affect billing and payment rules under both Medicare and in Medicaid programs such as Medi-Cal in California, with provider-based facilities typically entitled to higher payment levels, or entitled to receive facility fees where freestanding facilities are not. New rules published by HCFA in the April 7, 2000, Federal Register for the first time codify in regulations HCFA's criteria or conditions that facilities must meet in order to be treated as provider-based. Informal statements issued by HCFA personnel indicate they will focus primarily on off-site facilities, will look at contracted facilities more quickly than those that are owned outright, and will consider distance or less direct involvement in management as indicators for priority attention. While this is a good indication of where HCFA is likely to look first, hospitals would be prudent, pending further clarification from HCFA, to prepare and submit to their Regional Offices a comprehensive set of applications for provider-based determinations applicable to all provider-based facilities and departments reported on their cost reports that have not previously received a specific letter from the Regional Office determining its provider-based status.

October 10, 2000 Implementation Date. The new provider-based determination rules are effective October 10, and there may be significant benefits in requesting a determination prior to that date, as discussed below. The forms required may be substantial and lengthy, and it does not seem logical that HCFA means for hospitals to apply for each of the departments and facilities that are reported as provider-based on the cost report, are located in the main building or on the hospital's main campus and are fully integrated into the hospital's licensure, governance and professional supervision. However, that is what the new regulations appear to contemplate. In recent conversations, HCFA regional office representatives have indicated that such determinations should take the form of letters from HCFA, at least since 1998, when HCFA began requiring completion of a questionnaire to assist in determining provider-based status. Prior to 1998, Region IX office personnel indicate that such letters were not typically issued, and therefore provider-based entities have not likely received a HCFA determination as required. One Region IX official stated that, for this reason, facilities and departments that became provider-based prior to 1998 would be "suspect."

Determination Required. This may come as a surprise to providers whose provider-based entities have had that status for many years or decades. While HCFA's main concern is with the off-site and/ or contracted facilities identified above, its regulations do not except any department or facility from the re-

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quirement of securing a determination of provider-based status, although a "good faith" exception, discussed below, will protect some facilities and departments that lack a determination from the direst consequences, and certain on-campus departments that account for less than 5 percent of total costs on the cost report may by inference not be required to secure separate designation, although the authors are awaiting clarification from HCFA on this point.

Note: A letter from HCFA now has been received. It is attached as part of a supplement to this article.

Regulation Section 413.63(b)(2) requires a specific determination of provider-based status. Specifically, it provides:

> "A main provider or a facility or organization must contact HCFA and the facility or organization must be determined by HCFA to be provider-based before the main provider bills for services of the facility or organization as if the facility or organization were provider-based, or before it includes costs of those services on its cost report."

The same section provides that a facility or organization "is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based." It also states that off-campus facilities used as a site of physician services of a kind ordinarily furnished in physician offices "will be presumed to be a free-standing facility, unless it is determined by HCFA to have provider-based status."

Start with a List of Provider-Based Departments and Facilities. As a practical matter, hospitals would be prudent to compile a list of all outpatient departments and all facilities and organizations that it reports on its cost report as provider-based. All those that are off-campus, have management contracts with other entities, are joint-ventured, or are essentially physician practices should be attended to with the highest priority. Compliance with the new provider-based status regulations should be reviewed and also whether the specific facility or organization was determined by HCFA in writing to be provider-based. For those for whom no written determination can be found, an application should be submitted. Completion of the HCFA application will facilitate a determination whether the facilities are in compliance with all of the new criteria discussed below that they do not already meet. Even facilities that have been previously determined as provider-based will need to review the new criteria and comply with any new requirements, although compliance by October 10 is not as urgently required.

Other provider-based facilities, departments or organizations should also be reviewed. It may be that HCFA will require a completed application for each and everyone of these, as well. On the other hand, we have suggested to HCFA that it should clarify that certain types of fully integrated on-campus departments that meet all the requirements will be presumed to be provider-based, even without a formal determination. Or perhaps with HCFA's permission all such departments and facilities for which there does not appear to be a question about provider-based status can be covered by one common application, thus simplifying the paperwork for both provider and HCFA.

The greatest potential exposure presented by these new rules arises with respect to facilities such as off-campus physician offices or contracted home health agencies that have been billed as provider-based, but never previously determined by HCFA to be entitled to that status. In addition, provider-based skilled nursing facilities that are not within the main hospital building, but perhaps enjoy grandfathered provider-based status under state licensing law as being within 400 yards of the main hospital, should also be specifically addressed prior to October 10. If they lack a specific determination by HCFA and any such lack of determination of provider-based status for such facilities is not remedied or at least applied for by October 10, the facility may owe back to Medicare and/or Medicaid all prior payments received attributable to defective provider-based status for every cost reporting period subject to reopening.

Such recoveries will not be made for periods prior to October 10, 2000, if during all of that period management made a *good faith effort* to operate the facility as provider-based, meaning that, despite the lack of prior HCFA determination, the licensure and public awareness criteria, discussed below, were met; all facility services were billed as provider-based; and all professional services were billed with the correct site-of-service indicator. Note that, for physician office type practices, erroneous billing by one or more physicians using the wrong site-of-service indicator, e.g., claiming both professional and technical components when only the professional component should have been billed, may prevent the good faith exception from applying.

After October 10, 2000, facilities that have not been determined to be provider-based by HCFA, but which continue to be billed as such, will make the main provider subject to notice of the problem when HCFA becomes aware of it, adjustment of payment, and a determination whether the facility is provider-based. If a facility that has been treated and reported as provider-based is found not to be provider-based, notice will again be provided, and the provider-based treatment must then cease with the first day of the following cost reporting period, not to exceed six months from the date of notification.

New Definitions. Among new definitions contained in the new rules is one for "campus," defined as the area "immediately adjacent" to the hospital's main buildings, other areas that are "within 250 yards" and other areas determined on a case-by-case basis. In California, the former certificate of need process used a 400 yard standard for "adjacent to," and state rules for consolidated licensure also referred to this standard. Various facilities may have been licensed and/or certified as hospital-based under this old standard, but may not meet the 250 yard standard. These may be candidates for HCFA's new case-by-case determination. The rules also newly define the following terms "department of provider," "free-standing facility," "main provider," "provider-based entity and status," and "remote location of a hospital."

For hospital clinics that are off-campus, "incident to" rules (precluding reimbursement for certain services, unless "incident to" physician services), which are liberally considered to be met for all services within the hospital, are applied more restrictively, requiring direct supervision by a physician on the premises, although the same specialty is not required.

Regulatory Criteria. To qualify as provider-based, a facility and the main provider must meet several criteria. They must be subject to *common licensure*, unless where state licensing requirements either prohibit a single license, or do not permit licensure of the particular department or facility. The facility must be *under the ownership and control of the main provider*. This prohibits joint ventured departments or facilities from qualifying for provider-based status, since 100 percent ownership by the main provider is required. Also required is a single governing body, presumably the main provider's board of directors, and one set of organizational documents and final approval processes for such matters as contracts, medical staff appointments, personnel actions and administrative decisions.

The provider-based facility must also be subject to the main provider's *administration and supervision*. In addition to direct reporting requirements, supervision and oversight, the provider-based entity's administrative functions must be integrated, specifically including *billing services, records, human resources, payroll, employee benefit package, salary structure and purchasing*.

Clinical services must also be integrated, as shown by medical staff members of the provider-based entity having privileges at the main provider, subject to oversight and monitoring by the main provider and its clinical committees, any medical director of the facility having a reporting relationship to the main provider's chief medical officer, medical records being integrated, and access by facility patients to all services of the main provider. *Financial integration* is required, evidenced by shared income and expenses, and cost reporting of the facility in a cost center of the main provider.

Public awareness is an area of primary emphasis of the new rules. Patients should be aware that they are entering the main provider and will be billed accordingly. Typically, provider-based clinics carry higher facility fees than physician office tech-

nical components, and thus copayments are higher. *Location in the immediate vicinity* is also required, meaning on the main provider campus, or in other remote locations subject to specific complex rules for judging remote locations, involving analysis of admitting patterns from various zip codes.

Special rules also kick in when facilities utilize *management contracts*. In addition to the integration of administrative supervision requirements discussed above, the management entity cannot employ the facility's staff, with the exception of management personnel, and the management agreement must be with the main provider, not some affiliate or parent.

Similarly, a provider-based entity cannot rely entirely on services delivered *under arrangements*. In the home health agency context, for example, certain core services must be delivered by provider employees, and only select services may be delivered under arrangements where a management contract is in place.

New EMTALA Obligations For Certain Provider-Based Facilities. In a hospital's decision making process to determine whether to seek a determination from HCFA that an off-campus facility is provider-based, the provider should keep in mind that for some of these facilities, new and existing obligations under the Emergency Medical Treatment and Active Labor Act ("EMTALA") will attach to the facility and hospital once provider-based status is conferred. Deep within the final Outpatient PPS regulations are amendments to HCFA's EMTALA regulations which will place burdensome new EMTALA obligations on these hospitals and their provider-based departments.

New EMTALA Obligations Only Attach to Provider-Based Departments. When HCFA made the decision to impose additional EMTALA obligations on hospitals and their provider-based entities, HCFA only imposed these obligations on hospitals with provider-based departments. "Departments" are defined in the new regulations as those entities that furnish the same type of health care services as the main provider. "Departments" must be distinguished from "provider-based entities," which furnish health care services of a type different than that furnished by the main provider. Examples of a provider-based entities include hospital owned skilled nursing facilities or home health agencies. In the preamble to the regulations, HCFA specifically stated that no EMTALA obligations would attach to these provider-based entities.

The regulations also make it clear that for the additional EMTALA obligations to attach, the off-campus department must have provider-based status, as determined by HCFA. Consequently, a provider may be faced with a situation where it has one outpatient department, such as a clinic, that has a HCFA provider-based determination and a similar clinic that does not. In this situation, the additional EMTALA requirements would only attach to the first clinic.

EMTALA Obligations For Departments Should Be Met When Other Provider-Based Requirements Are Met. As discussed in the preceding section, if HCFA determines that an entity is entitled to provider-based status, that status may be conferred retroactive to the date the application for provider-based status was submitted, if all requirements to obtain provider-based status were met on that date. However, where the designation is being sought for a department, neither the regulations nor the preamble make it clear whether the additional EMTALA requirements will be imposed retroactively as well. Hospitals are therefore faced with a decision as to when to implement the new EMTALA obligations for these departments that are pending a HCFA provider-based determination.

Because there is a potential for retroactive application of the new EMTALA obligations, a risk adverse approach for providers is to ensure that at the time when all requirements to obtain provider-based status for a department are met, the additional EMTALA obligations for that off-campus department are met as well. This practice will ensure that there is no EMTALA compliance "gap" between the date provider-based status is conferred and the date the new EMTALA obligations are met.

Whether HCFA would actually enforce a retroactive violation of EMTALA is unknown, how-

ever, the potential fines and potential exclusion associated with EMTALA violations may not be worth the risk of delaying EMTALA compliance until after a HCFA provider-based determination. This is especially true where a provider is confident that all requirements to obtain provider-based status for a department are met.

New EMTALA Obligations. The new EMTALA obligations for hospitals with a provider-based department are set forth in some detail in the new amendments to the EMTALA regulations. The regulations include within the definition of "comes to the emergency department," a person coming to a hospital department with provider-based status. Therefore, if a hospital outpatient clinic does have provider-based status as determined by HCFA, any person who comes to that clinic requesting emergency medical services should be treated in the same manner as any person requesting emergency medical services who has walked into the emergency department of the main provider hospital: a medical screening examination should be given, if necessary an emergency medical condition should be treated and the patient should be stabilized or appropriately transferred. However, in addition to these requirements, the regulations impose additional requirements unique to the off-campus department setting.

Capability of Outpatient Department Includes Entire Hospital. Under EMTALA, a hospital has an obligation to provide, within its capabilities, a medical screening examination, and necessary stabilizing treatment for an emergency medical condition to a person who comes to the emergency room and requests emergency medical services. In these regulations, HCFA has made it clear that for purposes of a provider-based outpatient department, the "capability" of the department includes the capability of the entire hospital.

Currently, many provider-based departments that do not have the capability of providing emergency medical services to a person who presents with an emergency medical condition simply call 911 when presented with this situation. Under the new regulations, it appears that this practice would not be sufficient if the department's main provider does have the capability to screen and treat for the condition. One might question the wisdom of discouraging the use 911 procedures, since in many circumstances these may well result in the fastest delivery of necessary emergency treatment to the patient.

As discussed below, HCFA is requiring specified off-campus department protocols for these provider-based department in furthering this concept of extending the capability of the main hospital to the off-campus department. While implementing these protocols, it is important for the provider to ensure that all personnel are aware of the changes to present procedures in emergency situations. Training on these new protocols should be incorporated into a hospital's EMTALA compliance program.

Off-Campus Departments Must Have Protocols For Handling Emergency Cases. For these off-campus provider-based departments, HCFA is requiring certain procedures and the implementation of protocols for emergency cases. These protocols must provide a method for the off-campus department to directly contact the main hospital's emergency departments. Also, HCFA states in its regulations that the protocols may call for the dispatch of emergency medical personnel from the main hospital to the off-campus department if needed. According to HCFA, allowing a hospital to send emergency medical personnel to an off-campus department provides the hospital with flexibility when faced with these situations.

In addition to being given protocols, off-campus departments that are routinely staffed by physicians, RNs or LPNs must train these personnel to handle emergency cases. During normal hours of operation, at least one person in these departments must be designated to provide a medical screening examination, stabilizing treatment, or if required, certification in accordance with EMTALA that a transfer is required.

Off-Campus departments such physical therapy, radiology, or other facilities that are not routinely staffed by physicians, RNs or LPNs must have protocols that require the staff at these facilities to contact the emergency department and describe pa-

tient appearance and symptoms. The staff also must assist in the transportation of the patient to either the main hospital or the appropriate transfer of the patient under EMTALA.

It is obvious that hospitals will need to modify current EMTALA training programs to accommodate these new requirements. In doing so, hospital administrators should ensure that all staff in these off-campus departments are trained in all facets of EMTALA, such as restrictions on delaying treatment in order to request financial information, maintenance of the central log for emergency medical service requests, and attempting to obtain informed written consent when a patient refuses a medical screening examination or treatment. Off-campus department staff also should be trained on the proper method of responding to patient inquiries regarding financial responsibility for the emergency medical services, particularly in light of the guidance on this issue in the recent HCFA/OIG Special Advisory Bulletin.

Procedures For Moving Patient Varies Depending Upon Location. There will undoubtedly be many situations where the off-campus department does not have the resources on site to conduct a complete medical screening examination or provide the necessary stabilizing treatment for an emergency medical condition. In these situations, the patient must be moved from the off-campus department to either the main hospital facility or an alternative hospital.

If the main hospital has the capability required by the patient and movement of the patient to the hospital would not significantly jeopardize the patient's life or health, the patient must be taken to the main hospital. HCFA specifically states that transportation of a patient from an off-campus department to the main hospital is not a transfer under EMTALA but simply a movement of the patient between departments in the hospital. Therefore, the EMTALA transfer certification requirements do not need to be met. However, appropriate transportation to the main hospital must be provided to the patient.

Hospitals should avoid advising a patient who needs emergency treatment to drive to the main hospital in his or her own vehicle in these situations where the patient has not been given a complete medical screening examination to determine whether or not an emergency medical condition exists or where one does exist, treatment necessary to fully stabilize the patient has not been provided. Doing so would likely be viewed as a constructive denial of providing either the screening examination or treatment in violation of EMTALA's requirements. Hospitals should ensure that proper ambulance transportation exists for these situations. Of course, the delineation between those who seek emergency services and those who seek non-emergency services requires some medical judgment. Anyone sent to walk or drive to other departments who turn out to have had emergency conditions may generate complaints of EMTALA violations against the hospital.

In situations where the main hospital does not have the capability required by the patient or where the patient's condition is deteriorating so rapidly that movement to the main hospital would significantly jeopardize the life or health of the patient, then the patient must be transferred to an alternative facility. In these regulations, HCFA requires protocols to be established for these transfers. HCFA also requires hospitals to have agreements in place with other hospitals or medical facilities near the off-campus department to facilitate these transfers. The transfer must either be requested by the patient, or meet the normal EMTALA transfer certification requirements.

The requirement of pre-existing agreements may eliminate one requirement of an appropriate EMTALA transfer: that the receiving hospital agree to accept the transfer. However, prior to the transfer, the transferring hospital should maintain its present practice of contacting the receiving hospital as required by EMTALA to ensure that the receiving hospital has the capability to receive the patient.

Current EMTALA Obligations. When implementing the requirements in these new regulations for off-campus provider-based departments, a hospital should ensure that it does not overlook implementation of the current EMTALA obligations in the off-campus departments as well. Emergency department registration procedures should be implemented. Restrictions on obtaining prior authorization for emer-

gency medical screening and treatment must be adhered to. EMTALA signage as well as central log requirements also must be met for the department.

Conclusion. The new provider-based entity regulations require prompt attention by providers to check whether existing provider-based entities have been determined as such by HCFA. If not, efforts should be taken to remedy this situation prior to October 10. Even if they have been determined to be provider-based by HCFA in the past, providers should also review the new rules, and implement any changes required by them. Among those new changes are the extension of EMTALA requirements to all provider-based departments.

Supplement to Article

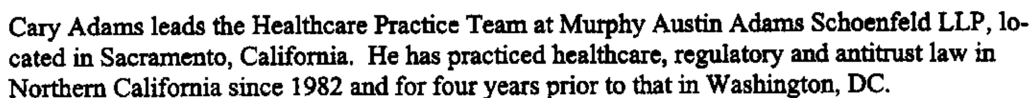
HCFA Clarifies that All Provider-Based Departments and Facilities Must Apply to the Regional Office for Provider-Based Status, Except for Those on the Main Campus Whose Costs Add Less Than Five Percent to Total Costs Reported on the Cost Report.

Cary M. Adams & Anthony M. Perez

In a letter dated July 28, 2000, HCFA Region IX has clarified that, to comply with new Provider-Based Entity regulations issued April 7 and effective October 10, all provider based departments and facilities, regardless of how long they have been treated as provider based, must apply for and receive written designation as provider-based, with the sole exceptions of departments and facilities on the main campus whose costs when added to the cost report increase total reported costs by less than five percent or those who have received specific written designation beginning in 1998. To avoid compliance issues, providers would be wise to make such application prior to October 10, 2000. Despite this pressing deadline, HCFA Region IX now indicates that a new nationwide questionnaire/application under development may not be available until after October 10. In the meantime, providers should use the "Questionnaire for All Provider-Based Designation Requests" previously published as part of Program Memorandum A-99-24, dated May 1999. HCFA also has informed us that further guidance regarding this topic will be provided shortly in the form of "Q's and A's" listing commonly asked questions and HCFA's responses to those questions.

A copy of the HCFA Letter, from Wayne Moon of Region IX, is attached for your information. This note and that letter should be regarded as supplemental to our earlier article on this topic, which was initially published in the July 2000 issue of the HFMA, Northern California Chapter's on-line newsletter, *Over The Edge Brief.*

Neither this supplement, nor our prior article, constitutes legal advice.



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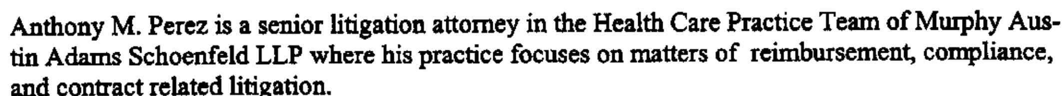

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Division of State Operations

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July 28, 2000

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Re: Provider-Based Determinations

Dear Mr. Adams:

We received your July 25, 2000 letter and appreciate your concerns and desire for clarification of the April 7, 2000 published provider-based regulations (Federal Register, Volume 65, Number 68), which goes into effect October 10, 2000. Your concern, as I understand it, pertains to the status of long-standing "provider-based" departments and facilities, most of which are located within the hospital or on the main "campus" and have always been reported on the cost report.

The first question is whether an entity has been designated as provider-based by the Health Care Financing Administration Regional Office (HCFA RO). The provider must have a letter from HCFA RO granting provider-based status for the specific entity (identified by name and address). Letters dated prior to 1998 would be "suspect". Those without a designation letter would need to seek provider-based designation. Having the entity reported on the cost report as part of the hospital does not and will not mean the entity has provider-based status unless specifically granted by this Office.

In reviewing the entities, the provider should first determine whether the individual entity is on the campus of the provider as defined by 42 CFR 413.65(a)(2). Under this definition, the entity is considered on the campus of the provider if it is located within 250 yards of the main building. If the entity is not on the campus and has not been designated as provider-based by the Health Care Financing Administration Regional Office (HCFA RO) in 1998 or later, the provider will have to seek provider-based designation for the entity. If the entity is located on the campus as defined in the new regulation, the provider will also need to seek provider-based status for the entity if the inclusion of the costs of the entity in the provider's cost report increases the total costs on the provider's cost report by at least 5 percent (42 CFR 413.65(c)(1)). If the inclusion of the costs of the entity in the provider's cost report does not increase the total cost on the provider's cost report by at least 5 percent, then the provider would not have to seek provider-based status for the entity.

For further clarification concerning various aspect of the new regulation, a Question and Answer (Q&A) web page will be set up in the next 2-3 weeks on the HCFA web page (www.hcfa.gov).

Currently, a national provider-based questionnaire/application is under development and may not be available until after October 10, 2000. However, keep in mind that all entities are subject to the current provider-based requirements promulgate in the Program Memorandum A-99-24, dated May, 1999 until October 10, 2000. Enclosed is the "Questionnaire for All Provider-Based Designation Requests" which may be used for seeking designation. All entities which have not been designated prior to October 10, 2000 will be subject to an evaluation based on the new regulation. The provider will be notified if additional information is required for an evaluation to be completed on a submitted questionnaire. All entities which have been granted provider-based status prior to October 10, 2000 will be expected to come into compliance with the new regulations without further notification from HCFA RO other than what has been or will be published in the Federal Register.

If you have any questions regarding this matter, please contact Emery G. Lee of my staff at (415) 744-3702.

Sincerely,

Wayne Moon, Director
Hospital and Community Care Operations