

November 3, 1998

Health Care Financing Administration
Department of Health and Human Services
Attention: HCFA-1005-P
P.O. Box 26688
Baltimore, MD 21207-0488

Dear Sirs:

The following comments have been prepared by the staff at Abbey & Abbey, Consultants, Inc. in connection with the September 8, 1998, Federal Register entry for the “Medicare Program; Prospective Payment System for Hospital Outpatient Services; Proposed Rules”.

Comments have been developed within the time constraints of the 60-day comment period. With the significant volume of the proposed rules and the technical nature of these rules the 60-day time period is not sufficient to adequately analyze and comments to all of the proposed rules. It is suggested that the comment period be extended.

Four copies of the comments have been provided. If the comment period is extended, additional comments will be provided relative to the APC groupings and weights. Analysis of these groupings and weights is currently in progress.

The following comments are provided in the order in which the subject matter was presented in the Federal Register entry.

- V. Hospital Outpatient Prospective Payment System (PPS)
 - A. Scope of Services Within the Outpatient PPS
 - 1. Services Excluded from the Hospital Outpatient PPS

MedPAC Recommendation Concerning Payment For Allied Health Professionals - The use of a separate cost pass-through arrangement appears to be appropriate. An alternative would be to provide a fixed per-APC weight override for services provided in settings where such training and education activities are provided.

- 2. Services Included Within the Scope of the Hospital Outpatient PPS

3. Hospital Outpatient PPS Payment Indicators

Incidental Services

There are a number of services categorized as incidental services which are 'packaged'. These services really seem to fall more into the classical APG category of consolidation.

It is noted that among the CPT codes that are proposed to be classified as 'incidental services' that are packaged into the APC rate are the 29000 series codes for casting and strapping. These codes should be grouped and paid separately under the APC system. For instance, a patient may be presenting for re-casting of a fracture that was addressed in an earlier visit (the initial casting may or may not have been performed at the given hospital). Since the patient is presenting for recasting there are significant resources being utilized both for the medical visit and the surgical process of re-casting. It could be grossly unfair for certain hospitals which may not be providing the initial services to then have to provide subsequent, post-operative services without appropriate compensation.

It is suggested that the basic philosophy of APCs be that whenever there is an encounter that the services provided by hospital are coded and appropriately paid based upon the given encounter. In the case of the casting and strapping codes, the only way in which such services should be packaged or consolidated is if there is a formal Global Surgical Package definition. With a GPS definition the initial hospital providing the service can then be paid for the post-operative care (the recasting in this case) and thus be responsible for such care. As with physician payment the series of "-54", "-55" and "-56" modifiers can be used to appropriately breakout and pay for services.

B. Description of the APC Groups

1. Setting Payment Rates Based on Groups of Services Rather Than on Individual Services.

The use of groupings is quite acceptable as long as the relative values or weights in this case have been developed upon a sound, consistent and verifiable set of data. Charge data refined with the use of Cost-to-Charge Ratios from hospital cost reports along with the CPT/HCPCS codes being submitted are quite appropriate. Each of these three areas of data is certainly suspect as discussed later in these comments.

The biggest difficulty in amalgamating individual types of services into categories is the degree and amount of bundling. For APCs all supplies and pharmaceutical (except chemotherapy drugs) are being bundled. Since there are supplies and pharmaceuticals whose cost vastly outweighs the 'average' payment for the service with which they are associated it is possible that certain hospital will be injured financially through an over application of 'averaging' payments into a given category.

For example, cataract surgery (CPT=66984) has a fairly uniform set of resources utilized in terms of room, staff, supplies, IOL, drugs, anesthesia, etc. Certainly an 'average' payment for cataract surgery and/or the APC into which it is categorized is appropriate. However, the Emergency Department treatment of a patient with a myocardial infarction can vary significantly. A smaller rural hospital may treat the patient with several doses of TPA and then transfer the patient. In such a situation the hospital may end up being paid only for an ER visit without due compensation for the very expensive TPA that was used. Similar situations occur with services like IV Therapy where expensive drugs are provided although the base service does not justify a high payment.

It is imperative that if an 'averaging' system is to be used such as APCs then there must be a cost outlier mechanism in place to provide extra payment for potentially variable and expensive items being included in the categorization. For APCs this means expensive supplies and pharmaceuticals should be subject to a cost outlier payment mechanism.

4. How the Groups Were Constructed
5. Packaging Under The Groups

Outpatient Self-Administrable Drug Waived Payment Comment – The process of allowing hospitals to waive payment for self-administrable drugs would certainly be welcome. This needs to be established as a safe harbor probably in a more generic sense. If a hospital elects to not charge, must they do such for all patients? For all Medicare patients? Or can they selective waive the charge based upon individual needs?

Packaged Services by Revenue Center – The packaging list is certainly extensive. With good data (see above) this should not create a problem except with expensive supplies and pharmaceuticals which should be subject to cost outliers.

It is notes that RCC=762, Observation Room, has been included in every category (surgery, medical visit, diagnostic, radiology, other). This **is absolutely incorrect**. Observation services have their own CPT codes and represent a separate and distinct service with medical necessity and associated documentation requirements. In the hospital outpatient setting this is a separate set of resources that are utilized. It is possible that observation room could be bundled into surgical cases that require anesthesiology when there is a complication post-operatively requiring additional observation. However in the other settings, payment for observation services should be made separately. For instance, consider the following two examples:

- a. Patient is seen in the ER, triaged, treated and then a decision is made to admit the patient to observation based upon diagnostic information;
- b. Patient is sent directly from a clinic (hospital-based or independent) to the hospital for observation services.

In both cases additional, separately identifiable resources are being used in the care of the patient and thus the hospital should be separately reimbursed for these services.

Payment should be based upon an hourly rate an directly correlated to the three levels of CPT code 99218, 99219, 99220. It is also suggested that there be two different payment levels within this series of codes. One for basic observation services (typically provided on an acute care floor) and one for advanced cardiac care where the observation is performed in an ICU or CCU.

6. Treatment of Clinic and Emergency Visits

Clinic and ER visit payments for outpatient services correctly represents one of the most complicated areas for APCs or APGs. There are several different aspects that must be carefully considered including several that have never really been addressed with APGs.

Establishment of Coding, Billing and Documentation Standards for Outpatient Coding

Much of the difficulty in using CPT/HCPCS, either in conjunction with or without ICD-9-CM diagnosis codes are part of the grouping process, lies within the fact that:

- a. There are no explicit coding policies for outpatient use of CPT/HCPCS,
- b. There is significant inconsistency in the FI requirements for submitting various CPT/HCPCS along with delineated charges which means that there need to be established billing policies relative to the use of CPT/HCPCS code;
- c. There are no documentation guidelines and/or standards for hospital coding documentation guidelines.

Coding Policies – The use of CPT/HCPCS codes for professional, physician claims development is different from their use for hospital outpatient facilities, technical claims development. Physicians generally code for what they do or the service performed. Hospitals code to indicate the resources utilized. Thus, for a given service during an encounter the physician and hospital may be using codes from the same sequence of codes (e.g., ER visit) but the codes may be different because the ER physician was only peripherally involved (physicians can bill only for services *personally* provided) while the hospital expended extended resources.

FI Requirement/Billing Policies – It is imperative that all FIs across the country be required to accept and have as a policy the full and correct coding of encounters. Currently there is a great deal of inconsistency particularly in accepting both E/M codes along with surgical CPT codes. Additionally, in many cases the FI requires that the charges be rolled into a single line item per RCC. This must change immediately! If the payment system, APCs in this case, are to be dependent upon data gathered through the claims process, then it is imperative that all codes be used and that there be charges attached to each code submitted.

Hospital Coding Documentation Guidelines – Just as there are documentation guidelines for physician coding, there should be the analog on the hospital side for the documentation standards for using CPT/HCPCS codes. For instance, in the ER in the provision of critical care services along with CPR (cardiopulmonary resuscitation), the standards for coding CPT=99291/99292 along with CPT=92950 need to be established. In many instances the coding will be the same as the physician although there could be differences. For example, observation services following ER services where the physician is not allowed to code both the observation admit along with the ER level of service. However, the hospital will code both since the two codes correctly indicate the resources being used.

Correlation of Physician and Facilities Coding – See comments below.

Multiple Clinic Visits On Same Day

Of extreme importance is for APCs to properly recognize and pay for multiple clinic visits on the same day (assuming that there is a 1-day window of service). Section 6, Comments on Specific APCs, “APCs with a status indicator of “V””, addresses this question to an extent. The proposed rules indicate that the hospital must file separate claims for the services. This will place a significant burden on hospital billing functions as to the determination of whether separate claims should be filed.

Additionally, the phrase “different diagnoses” is used in separating clinic services to be billed separately. The concept of “different diagnoses” will need to be explicitly defined and issued as a policy statement. The normal usage is “unrelated diagnoses”. This concept will need to be defined in algorithmic form for programming into the adjudication software. Thus the adjudication software can then appropriately pay for unrelated services.

Since there will probably be exceptions to the case, it will be necessary to allow the hospital to bill for services that are separate and even unrelated although there may be no definitive diagnostic difference. For instance a patient may be seen in a family practice clinic for abdominal pain and then be subsequently sent to a gastroenterology clinic for a more detailed work up. Both the family practice and gastroenterology clinics have taken up separate resources. This will probably require the use of a modifier such as “-59” on a claim form to indicate that the service was separate from any others on the date of service.

Another approach would be to separate services based upon the specialty of the physician involved. If different types of clinics are being provided by physicians/providers within different specialties, then certainly the services are separate and both should be paid. The primary problem here is that of billing for the services and the associated adjudication software.

Medical Visit With Surgical Procedure

Under APGs the DRG logic was used so that when there was a medical visit along with a surgical service, the medical visit was lost. As indicated on page 47569 of the September 8, 1998, FR

entry, medical visits are paid when the “-25” modifier is used. It should be made explicitly known that the use of “-25” modifier does not require a separate or distinguishing ICD-9-CM diagnosis code (see change in definition in 1999 CPT Manual). As long as the services are provided as separate and distinct and there is appropriate documentation the medical visit along with the surgical services should be payable. This will be particularly useful in ER setting where there is often a medical visit with minor surgical procedures.

The assumption that medical visits should not be paid on the same day as surgical services is overreaching even with the language of ‘scheduled’. It is quite possible that a patient might be seen in the morning for diagnostic medical services and then to have a ‘scheduled’ operation in the afternoon. Since this is the very beginning of a ‘Global Surgical Package’ definition, the definition should be carefully crafted. The use of “-57” modifier should be used and recognized, that is, if a physician sees a patient for a medical visit (office visit or consultation) and the decision to perform surgery results from this visit, then the visit should be fully payable.

Consideration should also be given to pre- and post-surgical bundling and windows. It would be much better to have a unified, well-defined GSP definition in conjunction with APCs. It would also be beneficial to have this outpatient GSP correlate to the coding and payments for the physician GSP.

Coding System To Drive Grouping/Payment

The coding system that is used to drive medical visit (including ER) payments depends almost totally upon the data that is available to correctly determine payment. The use of the CPT E/M should certainly be feasible. However, there have been no uniformly applied rules relative to using E/M codes for medical visits. Since payment has not depended upon the correct use of the E/M codes, the data gathered from claims would be wholly inadequate.

The use of ICD-9-CM codes alone again is feasible but will probably result in certain skewing of payments. For instance, there may be an initial visit with a diagnosis of cancer. There may follow a sequence of follow-up visits over a period of time with the same diagnosis. Is the initial, resource intensive visit to be paid the same as the less intensive follow-up visits?

The proposal of using a hybrid approach of first driving the general range of payment by an E/M code and then refining the payment

with the given range with a diagnosis code appears to be quite appropriate and should result in equitability of payments across many settings.

Non-Physician Services

Many services are provided in the hospital setting by non-physician providers ranging from general medicine provided by Physician Assistants and Nurse Practitioners, to specialized subacute wound care by certified nurses to transfusion services by nursing staff. The CPT coding system was developed by and for physician services. The only general medical service code for nursing services is CPT=99211. Care should be taken to provide coding mechanisms for these specialized service areas so that hospitals can appropriately bill and be paid for these services. The provision of these services by specialized, certified personnel increase the resources and costs incurred by the hospitals. There needs to be a mechanism to properly code for these services through APCs and to receive payment.

For example a specially trained nurse provides debridement services in a subacute wound care center that is a provider-based facility. Since this is a nursing service (indirect physician supervision) the CPT debridement codes cannot be used even though such services were provided and resources utilized. Since APCs provider facility payment through the use of CPT codes there needs to be a mechanism whereby such elevated and specialized nursing services can be recognized and appropriately paid.

Note that many of these do not involve the use of a physician. Thus there must be provisions as to what CPT/HCPCS codes can be used when there is no physician involvement. This needs to be done as an adjunct to the current special payment provisions for the currently recognized NPPs who are allowed to bill professional services on a HCFA-1500 if they obtain a provider number.

Correlation Of Physician And Outpatient Coding

A generalized compliance concern is that of the correlation between the physicians' services and the hospitals' services. It is certainly reasonable that the higher the level of services provided by the physician the higher the level of resources being consumed on the facility/technical side. Thus if a physician is providing a level 4 office visit then it is appropriate the facility level of service also be coded at a level 4.

The problem occurs when there is relatively little physicians involvement but a high level of nursing and/or other non-physician provider involvement (e.g., respiratory therapy) which elevates the resource utilization. If the CPT E/M codes are to be used as a part of the grouping process for APCs, then the hospital will need to be allowed to code at a higher E/M level than that of the physician. ***This means that E/M coding documentation guidelines will need to be developed for hospital outpatient coding since it may sometimes be different from the corresponding physician services and thus codes.***

This is not a problem with surgical services since both the physicians and hospital will be CPT/HCPCS coding in the same way (at least in theory).

Medical Visits With Observation Services

Great care should be taken to pay for both a medical visit (ER or outpatient clinic) and observation services. Physicians through coding guidelines in CPT are not paid for both the medical visit and the observation admit. This is primarily due to an overlap in the services being provided. If a physician has already performed a history, examination and made a decision of medical necessity through a medical visit, then meeting the observation documentation criteria carries over from the original medical visit.

On the facility side the situation is quite different since there is no overlap in the resources being utilized. If the patient is first seen in the ER and then moved to an observation bed, then the resources of both the ER and the observation bed are being utilized and payment should be made for both services. In this situation there will be no consideration of relatedness since both the medical service and observation services will probably be for the same diagnostic condition(s).

ER Triage/Assessment Fee

The ER triage or assessment fee should be paid for each encounter regardless of the disposition of the case. Since medical/legal liability is being assumed by both the physician and the hospital, it is appropriate that payment is made for this service. Having the assessment fee paid will also reduce any economic incentive to treat the patient in a manner that might maximize

reimbursement. Also current federal and state laws require ERs to see patients in order to do an assessment.

Erroneous Statement – Page 47567, Column 2, Top

There is a highly misleading and erroneous statement made concerning billing for ER level services even when the services are not emergent in nature. ***This statement should be retracted immediately!*** The whole reason for the development of RCC=456, Urgent Care In the ER, is to allow hospitals to appropriately bill for urgent care services in the ER. Note that RCC=456 requires the use of the regular 'Office Visit or Other Outpatient Services' CPT E/M codes. Similarly, if the ER is being used on a scheduled basis for a physician to meet with a patient then the services should be coded with the regular 'Office Visit or Other Outpatient Services' CPT E/M with RCC=510. This is a major compliance issue relative to medical necessity relative to billing for ER services. The implication of the statement in the Federal Register is that it is appropriate to charge for ER level of services even if the services are not emergent in nature!

7. Treatment of Partial Hospitalization Services
8. Comments on Specific APCs
9. Discounting for Surgical Procedures

The discounting schedule of 100%-50%-50%-50% is reasonable. The grouping process is complicated by the fact that some surgeries are subject to the discount while others are not. There should also be careful consideration relative to the 'add-on' codes as they relate to surgical procedures (see 1999 CPT). Care should be taken to not include such add-on situations with a reduction in payment for the add-on codes since these services are most likely an integral part of the original service.

Discounting for terminated procedures is certainly consistent with current payment policy. The use of the modifiers is appropriate.

10. Inpatient Care

The statement "Because observation is not provided as the sole service a patient receives, ..." is erroneous. There are many cases where a patient is admitted to observation status directly from a clinic setting (a clinic not associated with the hospital). Thus there

are definitely times when observation services are provided as a sole service. Since observation services consume separate resources from the hospital (separate from other services), observation services should be reimbursed separately in all cases. Obviously, there must be coding and documentation requirements developed in this area.

Inpatient services that are to be excluded from APC payment need to be reviewed with great care. While APCs have been developed as a payment system mainly for the elderly, this system may also be used for the non-aged population. Care should be taken to carefully examine the codes on the inpatient list. For instance, Laparoscopic Choleystectomy may be provided on an outpatient surgery basis and an APC should be developed even if certain cases are provided on an inpatient basis. The APC payment system should not force hospitals to perform services that could be provided on an outpatient basis as inpatient only to attain payment. The decision to provide the service inpatient versus outpatient should be driven only by medical necessity criteria. It is at the point of development of APCs that the broadest possible range of codes have payments developed. The continuing trend is for currently classified inpatient services to become outpatient services.

APC Payment System Interfaces

Further analysis should be given to assessing the payment interface between APCs and Inpatient DRGs, APCs and ASC payments and APCs and physician facility payments. The interface to these other payment systems needs to be smooth so that there is no economic incentive to perform the services in one setting versus another.

C. Calculation of Group Weights and Rates

The data used for the calculation of the APC group weights consists of the CPT/HCPCS, associated charges for the singleton occurrences and then also the Cost-to-Charge Ratios off Schedule C of the hospitals' cost reports. All three sets of data are highly suspect.

Charges across various hospitals and internally within hospitals are often highly inconsistent. The Cost-to-Charge Ratios on cost reports are often skewed through incorrect assignment of Revenue Center Codes (RCCs). Also, the outpatient coding is suspect. Even if the

coding is correct there are still problems with the way in which have been developed.

For example, in the ER on the facility side many hospitals have bundled all of the medical and surgical services charges into a single CPT code which may be a level code (9981-99282) or into a single CPT surgical code. FI requirements and delimitations on how the claims are to be filed have fostered this process. The associated charges may well represent multiple services. Thus, the choice of single occurrences may still produce misleading information.

It is imperative that with a system such as APCs that hospitals be required to fully code all encounters and that each code have an associated charge. In this way a proper data base of charge data can be developed.

D. Calculation of Medicare Payment Amount and Copayment Amount

1. Introduction
2. Determination of Unadjusted Copayment Amount, Program Payment Percentage, and Copayment Percentage
3. Calculation of Medicare Payment Amount and Beneficiary Copayment Amount

The proposed rules relative to copayment are overly complicated. If a phase-in of the copayment is to be made it should be made on a uniform basis for all hospitals over a period of years. The proposed approach may well take tens of years for full implementation and the overall approach and rules will most likely change before final implementation.

It is suggested that a five year phase-in process be adopted. This can well be correlated to the overall phase-in of APCs. The beginning copayment should be that payment that has already been calculated based upon current copayment amounts as appropriately trended forward. During each of the years of the phase-in the copayment amount should be reduced by a given percentage (25% for four years, 20% for five years, etc.) so that after the applicable number of years the copayment becomes 20% of the APC payment.

- E. Adjustment for Area Wage Differences
- F. Claims Submission and Processing
- G. Updates
- H. Outlier Payments

As discussed elsewhere in these comments, it is imperative that there be a mechanism established for the payment of expensive pharmaceuticals and supplies. While this could be accomplished on a coding basis (e.g. extended use of Level II HCPCs), it is more feasible to establish cost outliers on an algorithmic basis. This has been done for inpatient services under DRGs. While there are many algorithms that can be developed, certainly with any outpatient encounter where the supply and/or drug costs are equal to the expected APC payment, then the outlier payment should kick into place.

I. Adjustments for Specific Classes of Hospitals

Special classes of hospitals should be given due consideration. Extra compensation on a per APC basis and/or additional recognition through increase payment rates is certainly appropriate. The suggestion that APCs be phased into place for certain special classes of hospitals has merit. However, it would be better to use a four or five year phase-in for all hospitals. The most appropriate way to accomplish this process is to base part of the payment on the national rate and part based upon the specific hospital's costs.

An alternative to a phased implementation would be to set up a 'hold-harmless' process. For instance, in the first year of APCs any given hospital would be assured that there payments would be within a plus or minus 5% of the current payments. In the second year the percentage would be changed to plus or minus 10%, the third year plus or minus 15% and in the fourth year plus or minus 20%. Thereafter the payments for hospitals would be fully at the national geographically adjusted rate.

J. Volume Control Measures

Great care must be taken relative to any volume control measures. The experience with Physician Payment Reform under RBRVS is a clear indicator that such control measures can easily become political.

With in the approaches outlined in the Federal Register entry, the last alternative of developing a new SRG modified for hospital outpatient usage is most appropriate. There should be no behavioral offset at the time APCs are implemented. The changes involved with APCs are of such a significant nature that hospitals will have to make major adjustments in the billing, coding and reimbursement processes. With the developing of new coding and billing policies from HCFA there will also have to be changes in documentation requirements. Thus as much latitude as possible should be given to allowing hospitals to coding and bill so that they are appropriately reimbursed.

- VI. Hospital Outpatient Clinics and Other Provider-Based Entities
 - A. Background
 - B. Effects On Medicare
 - C. Relationship of the “Provider-Based” Proposals to Prospective Payment for Outpatient Hospital Services and Effective Date of “Provider-Based Proposals
 - D. Basis for Current Provider-Based Policy
 - E. Provisions of This Proposed Rule

There is certainly a legitimate need for further clarification in the area of ‘provider-based’ and/or an entity being organized as a part of a hospital outpatient department. There is a need for clarity in the rules and regulations. There is also a need for latitude in allowing hospitals and integrated delivery systems to organize for proper delivery of care without being constrained by artificial rules and regulations.

Certainly there should be an approval or determination process. It is imperative that there be a distinct time limit relative to the approval process. For instance, it should take no more than 30-days to make a determination along with a process for remediation of any potential deficiencies. The determination process should be such that for a new or acquired entity that if a negative determination is not made within 30-days, then the entity has been approved as a facility-based entity.

Ownership

Ownership of a provider-based entity should not be required on a sole ownership basis. Granted, the provider-based entity should be licensed, certified, accredited and operated by a given main provider. However, the ownership per se should not be required by a single entity. There may be very legitimate reasons why a joint venture or partnership arrangement of some sort is appropriate. Thus there should be latitude for such ownership arrangements assuming such arrangements do not violate any of the other numerous rules and regulations in this area.

Operational Management

The fact that the provider-based entity should be operated by the main provider and that it truly be a integrated part of that main provider is certainly appropriate. The two areas where there is sometimes confusion are:

- a. Integrated Medical/Patient Record Keeping System, and

b. Integrated Billing Systems.

The proposed language appears to address the medical records system by indicating that it is sufficient to have pointers to possibly separate medical record systems. In many instances the provider-based entity will have its own medical or patient record keeping system. As long as there are cross-reference indexes and pointers between the main provider and the provider-base entity, this should be sufficient. It is assumed that the medical record keeping function is under common management from the main provider.

There needs to be language that allows the same process for billing systems. In some cases the provider-based entity will be a medical clinic. The process of filing HCFA-1500 claims is quite different from the hospitals' process of filing UB-92. In many cases there will be different, specialized computer systems for each. If the rule requires that these systems be truly integrated, then what is the degree of integration? It would appear that the intent of the rule is to have common management as opposed to physical integration or networking of the systems. This needs to be made clear along with the indicators for such integration.

Similar situations also occur when the main provider and/or the provider-based entity use a third party for services in various administrative areas. For instance, if the provider-based entity in question is a medical clinic, it is quite possible that before acquisition by the main provider that the medical clinic used a billing service. There should certainly be no problem in having the same billing service used after the acquisition so long as the contract is switched to the main provider for such billing services. In other words the common management test has been achieved in this example.

Clear, Concise Rules – 30-Day Approval Limitation

It is imperative that rules and regulations in this area be clear and explicit so that arbitrary and sometimes different interpretations cannot be made. There also needs to be a short time frame for determination of such status by the Fiscal Intermediary and/or Carrier. It is suggested that a 30-day period be established for the FI to make a determination and that there be a time period for the hospital or other entity to make changes in order to meet the criteria set forth in the rules and regulations. It is important to establish clear rules and to have strict time limits so that this process does not become another level of complexity and delay in establishing delivery systems that are for the benefit of patients.

5% Rule

The five percent (5%) rule for reporting and gaining approval appears to be grossly artificial. Using a percentage approach will certainly assist large hospitals and hospital systems since any individual acquisition or development may fall under the 5% rule. A small hospital can hardly set up anything meaningful that would fall under the 5% rule. Thus a fixed dollar threshold should be used if there is to be such a standard. The alternative is to have all such acquisitions and/or developments be referred to the FI and/or Carrier for determination and approval. As long as such determinations have to be made within 30-days with default approval if further information is not requested and the rules are clear and consistently applied there should be no undue burden on hospitals and/or integrated delivery systems.

Note also that any requirement for reporting and gaining approval should be based on new acquisitions or developments. All facilities that are currently provider-based should remain so and be grandfathered into the new rules.

Common Licensure

The requirement for common licensure is absolutely inappropriate. Licensure is at a state level and there are significant differences between various states. The rules being promulgated here should be at a national level. A much better indicator for the provider-based status is that of common accreditation, which also requires common management. A simple example of the inappropriateness of common licensure is a situation where a hospital is located on a border city of a given state. It is quite likely that the hospital will have provider-based facilities across the border. It is inappropriate for such a hospital to be put at a disadvantage simply because a state border is involved. The payment system is at a national level and the rules and regulations should thus be at a national level and not be hampered by different state licensure considerations.

Catchment Area

The proposed rules place the burden of justifying the geographical proximity for provider-based status on the hospital. The language in the proposed rules appears to be somewhat arbitrary in terms of judging whether a facility meets the requirement of geographical proximity. In order to simplify this process it is suggested that a de minimus safe harbor be established relative to the geographic proximity. For any facility within the designated radius, no further justification would have to be made. For facilities outside the radius

the burden would be on the hospital to establish that the facility meets the geographical proximity requirements.

One way to do this is to establish three different classes of geographical location. The following classes are suggested with the defined radius:

- a. MSA – 30 Miles
- b. Non-MSA/Non-Rural – 60 Miles
- c. Rural – 100 Miles

With the implementation of such a de minimus rule the true cases where there might be some concern can more appropriately receive the considerations of both the hospital and the Fiscal Intermediary.

Retroactive Recoupment

The proposed rules indicate that the new rules for provided-based entities will go into effect 30-days following the publishing of the rules. This should be changed to the more standard 90-days. Also, once the new rules are in effect all facilities currently being considered as facility-based should be grandfathered into the new rules. Only after a determination has been made by an FI that the facility does not meet the requirements and the time period for remediating any deficiencies has past should there be any retroactive recoupment of payment. Any retroactive recoupment should be limited to the time at which the FI has indicated that provider-based status is not being met.

There should also be a formal process defined for hospitals to file for such determination. As indicated elsewhere in these comments there should be a 30-day time period for a determination as to status. If the provider-based status is not denied within the 30-days, then the hospital is allowed to proceed as provider-based with no penalties. With such a short turnaround time the hospital should be required to not start billing under the new arrangements unless approval has been received or the 30-day time period has expired.

Summary

While the overall process of refining and defining provider-based status is certainly laudable, it is important that the rules and regulations and the application of these rules and regulations not interfere with the development of integrated delivery systems and other joint venture arrangement that can enhance the efficiency and effectiveness of delivery. The payment system being used should not interfere with the development of delivery systems. Also, the application of the rules and

regulations must be uniform and consistent across the United States. There should be no variations in either rules, interpretation and/or application of the rules.

- F. Requirements for Payment
- VII. MedPAC Recommendations
- VIII. Collection of Information Requirements

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