

June 6, 2000

Hand-delivered

Attention: HCFA-1005-FC

Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: HCFA-1005-FC: Medicare Program; Prospective Payment System for Hospital Outpatient Services

Dear Ms. DeParle:

The American College of Emergency Physicians, the American College of Cardiology, the American Heart Association, the American Society of Nuclear Cardiology, the Society of Chest Pain Centers and Providers, and the American College of Physicians-American Society of Internal Medicine appreciate the opportunity to provide comments on the Prospective Payment System for Hospital Outpatient Services final rule that was published in the Federal Register on April 7, 2000. (HCFA-1005-FC).

We are submitting these comments jointly as an expression of our great concern that the new payment system inappropriately precludes separate payment for emergency observation services. We appreciate HCFA's willingness to meet with representatives of several of our organizations in early May to discuss this important issue. This letter represents our formal recommendations to HCFA in response to that meeting. In addition, some of our organizations are submitting comments to HCFA on other issues under separate cover. Briefly stated, this letter makes the following points about HCFA's policy of packaging payment for all observation services, including emergency observation services, into other APCs:

- It will jeopardize patient safety and quality care
- It will threaten access to medically necessary care
- It fails to recognize the increased costs of emergency observation services
- It will increase total Medicare costs
- It is inconsistent with current medical practice
- It is biased against observation services and the attempt to control abuse of some types of observation services by packaging all observation services is inappropriate.

We are proposing a policy that will be easy for HCFA to implement. Our policy will overcome all of the problems associated with HCFA's newly announced policy while eliminating the potential for abuse identified by HCFA in the final rule.

We are enclosing a detailed background paper in support of the points made in this letter. It summarizes the relevant medical literature and reflects the collective experience of numerous experts in the field of emergency medicine, observation care and cardiology. It is important to note that the outpatient prospective payment system has no direct effect on physician payment.

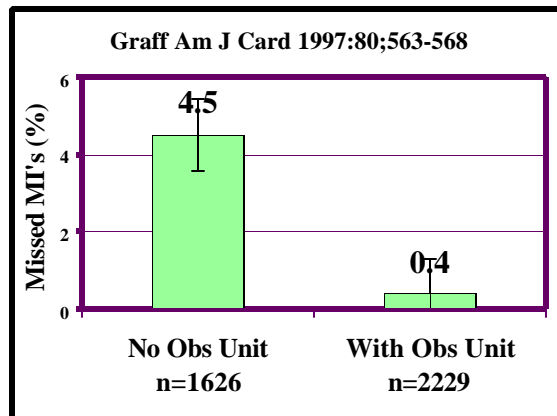
As such, HCFA should note that our objections to the agency’s policy and our proposed solution are being offered in the best interests of our patients and the hospitals who serve them.

HCFA's policy jeopardizes patient safety and quality of care

HCFA's refusal to provide separate payment for emergency observation services will inhibit their use and jeopardize the enhanced quality of patient care that derives from these services. Such a policy is inconsistent with the health policies of the current administration, which places a high priority on patient safety.

It is noteworthy that in response to the recent Institute of Medicine's report on medical errors, President Clinton took strong new steps to ensure patient safety through the prevention of medical errors. On December 7, 1999 the President held a meeting with health care providers and consumers; signed an executive memorandum directing a federal task force to submit recommendations on improving health care quality and patient safety; and directed federal agencies to evaluate, develop, and implement health care quality and patient safety initiatives. Secretary Shalala was co-chair of the federal task force. In light of the President's and Secretary’s personal commitment to quality care, it is particularly troublesome that HCFA would implement a policy that has the effect of jeopardizing patient safety, given the demonstrated successes of emergency observation services in enhancing patient safety.

Our position regarding observation services and patient safety is supported by published evidence in the medical literature. Observation of emergency department patients has been extensively studied and shown to provide improved health care outcomes. For example, as shown in the following table, the use of emergency observation services leads to a ten fold decrease in the error rate for “missed myocardial infarction” (the rate at which heart attack patients are inappropriately sent home). Preventable deaths and complications are avoided through the use of these services.



HCFA's policy threatens access to medically necessary care

HCFA's decision to package all observation services will create a disincentive to maintain current emergency observation services and will discourage the addition of these services to those hospitals that do not currently provide them. If the services are not separately covered, many observation units will close. Without separate revenue, emergency observation units will not be able to operate and progress made in this area of medicine over the last ten years will suffer greatly. If this service is not adequately covered, then HCFA will penalize physicians and hospitals for attempting to provide high quality, cost-effective health care to patients in need.

If emergency observation services become unavailable, the assumption is that many patients will be admitted as inpatients. Using an inpatient DRG to pay for this group of patients may be problematic for two reasons. First, if patients are admitted to an inpatient bed this will increase costs for HCFA. Second, many other third party payers (including HCFA carriers) are using increasingly stringent admission criteria (such as “Interqual”), which refuse inpatient admissions but allow observation. If HCFA is then refusing to provide reimbursement for observation services it is creating a growing void into which patients will fall. This policy will create a large, and growing, patient population who are too sick to go home but not sick enough to be admitted as inpatients, or for whom normal emergency evaluation is too short, but the normal length of hospitalization is unnecessarily long. Forcing emergency departments to provide up to 24 hours of uncompensated care will greatly increase the financial burden and gridlock in emergency departments. This will only further weaken the nations’ primary health care safety net, the emergency department. On the other hand, discharge will certainly lead to poor health outcomes. The current packaging of observation services creates an untenable position where hospitals and physicians will be forced to choose between two poor outcomes.

HCFA's policy fails to recognize the increased costs of observation services

For hospitals, there is a separate cost for providing emergency observation services that is greater than the cost of the emergency department visit. Traditional emergency services only involve the immediate care of acutely ill and injured patients, then admission or discharge occurs within 2 to 4 hours. In the past, these patients would have been admitted and used inpatient resources. The use of emergency observation services allows patient care to be moved from the inpatient setting to an outpatient setting with an overall decrease in cost for the patient visit. However this accelerated care over an additional 6 to 24 hours represents a significant increase in service and cost that is taken on by the emergency department.

The added hospital costs for emergency observation services come in the form of additional nursing, clerical, and support staff for services provided as well as construction and maintenance costs. Observation units typically staff with a ratio of one nurse per 4 to 8 patients. As the number of patients increases, additional clerical and support staff become necessary. This staffing ratio ranges between that of a regular medical-surgical floor and that of an intensive care step down unit. These staff would not be added were these patients to simply have been admitted. For proper operation, observation units usually require 100 to 150 square feet of floor space per room with support equipment. As the number of rooms increases a central nursing station is needed. Again, these are costs that would not have been incurred if inpatient admission were chosen.

HCFA's policy will increase Medicare costs

With observation, a portion of patients who would have been admitted can receive medically appropriate care and avoid unnecessary hospital admission. For example, most chest pain patients need extended emergency evaluation and observation or hospital admission to identify those acute MI patients who present with atypical signs and symptoms of their disease. The majority of patients with acute MI do not have a positive test upon evaluation in the emergency department. Thus physicians cannot rely upon initial test results alone. They must either admit patients to the hospital for a “rule out MI” evaluation when there is a suspicion of acute MI, or send the low risk patient home. Many chest pain patients with acute MI do not have typical clinical findings of acute MI. Nearly half of admitted chest pain patients without acute MI have a history or other initial findings which may be “classic” for acute MI. Thus in an “admit or

discharge” system the physician must admit patients to the hospital who do not always have typical features of MI, in order to avoid inadvertently sending more MI patients home. Acute MI patients with atypical presentations are identified during the extended evaluation with repeated blood tests, ECG monitoring, and physician reevaluation.

There is an inverse relationship between the proportion of chest pain patients who receive a complete evaluation (admitted) and the rate at which AMI is missed. In an “admit or discharge” system, the total costs directly increase as the physician tries to improve quality of patient care by increasing the proportion of patients admitted. Multiple studies have shown charge and cost savings with the use of observation rather than hospital admission to evaluate patients with chest pain. This is illustrated in the following table that shows the cost savings with avoided hospital admissions.

<u>Author/Year/reference</u> (references listed in enclosed background paper)	<u>Savings/ pt</u>	<u>StudyDesign</u>	<u>Costing method</u>
Kerns/1993/26	\$1,873	Contemporaneous	Charges
Hoekstra/1994/27	\$1,160	Contemporaneous	Charges
Hoekstra/1994/27	\$2,030	Contemporaneous	Charges
Rodriguez/1994/28	\$1,564	Contemporaneous	charges (mean IP)
Stomel/1999/29	\$1,497	Contemporaneous	Costing
Mikhail/1997/30	\$1,470	Historical	Costing
Sayre/1994/31	\$1,449	Contemporaneous	Engineered std.
Gomez/1996/32	\$1,165	Historical	Charges
Gomez/1996/32	\$624	Randomized	Charges
Gaspoz/1994/33	\$698	Contemporaneous	costs (detailed)
Roberts/1997/34	\$567	Randomized	costs (detailed)

Chest pain comprises only 10% to 15% of patients who benefit from emergency department observation units. The range of conditions evaluated and treated in emergency observation units is broad and includes the full range of conditions found in emergency departments.

Category	Conditions Observed
Evaluation of Critical Diagnostic Syndromes	Abdominal pain, chest pain, confusion, dizziness, fever, gastrointestinal hemorrhage, headache, seizure, shortness of breath, syncope, toxicology/overdose, trauma, vaginal bleeding, weakness
Treatment of Emergent Conditions	Asthma, congestive heart failure, dehydration, hyper/hypoglycemia, infections, pain management/back pain
Meet Psychosocial Problems and Needs	Alcohol abuse, psychiatric problems, social problems

Avoiding hospital admissions on patients with chief complaints other than chest pain by use of a period of observation has similarly been shown to have great cost savings. Since 5% to 10% of ED patients are appropriate for observation, the cost savings in the United States, which has over 100 million emergency department visits per year, runs into the billions of dollars. Clearly, a movement back to the inpatient setting will increase Medicare's total costs.

HCFA's policy is inconsistent with current medical practice

HCFA's discussion of observation services in the final rule demonstrates a fundamental misunderstanding of the current practice of emergency medicine. HCFA states:

“We assume that chest pain patients, such as those described by the commenters, are sent to the CCU or ICU for observation. We believe that, in general, if a patient needs to be monitored in the ICU or CCU for any length of time, then that patient should be admitted as an inpatient. Furthermore, we have never considered care furnished in an ICU or CCU to be outpatient services. Existing cost reporting instructions allow for the use of these specialty beds during a shortage of regular inpatient beds, but charges are to reflect routine care, not intensive care.”

It is simply untrue that most chest pain patients who would require observation “are sent to the CCU or ICU for observation”. There has been a fundamental change in health care delivery for chest pain patients with respect to the use of CCUs and ICUs in the last decade. Historically the CCU was developed over 30 years ago to care for patients with acute myocardial infarction and its associated complications. Over time, CCUs became filled with patients at low to intermediate risk for myocardial infarction, most of whom did not have serious disease. Attempts to expedite inpatient care were repeatedly met with failure, with average inpatient stays of 2 to 3 days under the best circumstance.

It has been found that these patients can be managed at least as effectively, at greater than half the cost, and in roughly 12 to 18 hours in a chest pain observation unit setting. Over time this approach has been embraced and encouraged by health care providers and payers. Recent studies have shown that roughly 22% of metropolitan emergency departments have a specific type of observation unit called a “Chest Pain Center.” It is estimated that a much greater percentage have a general Emergency Department Observation Unit. A move back in time to having these patients “sent to the CCU or ICU” will increase health care costs, increase missed heart attacks, and decrease patient satisfaction.

HCFA policy is biased against observation services and attempts to control abuse of some types of observation services by packaging all observation services are inappropriate

In the final rule, HCFA states:

“Observation service is placing a patient in an inpatient area, adjacent to the emergency department, or, according to some comments, in the intensive care unit (ICU) or coronary care unit (CCU), in order to monitor the patient while determining whether he or she needs to be admitted, have further outpatient treatment, or be discharged. After 1983, many hospitals began to rely heavily on the use of observation services when peer review organizations questioned admissions under the hospital inpatient prospective payment system. However, in some cases, patients were kept in “outpatient” observation for days or even weeks at a time. This resulted in excess payments both from the Medicare program and from beneficiaries who generally paid a higher coinsurance.”

We understand and appreciate the concerns expressed by HCFA regarding abuses of observation in the post-operative and inpatient settings. However, observation of emergency department patients over the time frame of 6 to 24 hours is a well-established practice that preceded the introduction of the DRGs in America. In fact it occurs in countries with emergency departments throughout the world - independent of a DRG based system. Recognizing these inherent flaws of

observation services in other settings has driven this area of patient care to dedicated units, often in the emergency department setting. It is here that observation services, as defined by HCFA, can be provided most reliably.

The undifferentiated nature of emergency department patients best fits the original description and intent of “observation services” set forth by HCFA. Emergency department patients present with a variety of symptoms such as chest pain or abdominal pain that may represent serious conditions, or illnesses such as infection, asthma, or congestive heart failure that require further treatment.

Emergency department and chest pain observation units do not generally “observe” post-operative patients. Observation of patients after an emergency department visit is distinctly different from post procedure observation services. Emergency department patients present with undifferentiated symptoms that require further testing or acute conditions that require further treatment. Unlike post-procedure patients, emergency department patients represent unscheduled visits.

Unlike inpatient observation status, it would be virtually impossible to keep a patient in an emergency department observation unit or chest pain unit for “several days to weeks” at a time. Because of the design of emergency department or chest pain observation units, many of the inefficiencies in rapidly managing observation patients in traditional inpatient beds are overcome.

Observation medicine, as it is developing in America, is a diagnostic tool where focused aggressive diagnostic testing or treatment is repeated over a specific timeframe to identify a patient’s need for inpatient admission. The primary intervention employed is time. It has been better studied and proven than many more expensive technical innovations for which HCFA has chosen to provide specific reimbursement. It is inappropriate to jeopardize this valuable service in an attempt to control the types of abuse noted by HCFA in the final rule.

Proposed solution

The objective of our proposed policy guidelines is to limit observation services to a small subgroup of patients (less than 5% of emergency department visits) who require continued clinical management to determine the need for admission or who need extended treatment of an acute condition. Encouraging this alternative to admission will avoid admissions and improve health care outcomes. There are six aspects of our proposal.

1. Clearly identify the observation services for which separate payment is appropriate

Hospitals presently report and bill for observation services through the use of revenue code 762 - Observation Services. Current HCFA instructions direct the reporting of the number of hours of service in the units field on the bill. This same revenue code is used to report postoperative or post-procedure observation services, emergency department observation services, "23 hour admission" services in an inpatient bed and holding unit services. Of these services, only emergency department observation services should be eligible for separate payment.

To clearly identify these services, we recommend the following:

- Create a new HCPCS code with the description "extended emergency evaluation and management services." A new HCPCS code is needed to distinguish these services from other observation services and to avoid conflict with the CCI edits that will

limit services to either emergency or observation, but not both. In addition, it will clearly distinguish the CPT codes used by physicians for emergency department visits and observation care services from the HCPCS code used by hospitals to report the additional overhead associated with extended emergency evaluation and management services.

2. Restrict services to emergency department patients

To eliminate the inappropriate use of the code to report postoperative care, 23-hour admissions to the inpatient area and holding units, we recommend the following:

- Limit the use of the new HCPCS code to revenue code 450 - Emergency Room. Other observation services would continue to be reported with revenue code 762 while further charge and cost data is collected by HCFA following the implementation of the new payment system. That data would be used to determine whether any further modifications of the payment policies for observation services were warranted.

3. Require extensive physician involvement in the services

In light of the clinical importance of extended emergency evaluation and management services, assuring direct, ongoing physician involvement is imperative. We recommend the following:

- The physician must document a discrete timed order to initiate extended emergency evaluation and management services. This order must precede observation services and a specific reason for observation must be documented in the chart (e.g., “chest pain”).
- The physician must document the performance of any periodic reassessments.
- The physician must document a discrete timed order to discharge the patient from observation or admit for inpatient care.

4. Restrict the service to patients whose length of stay (ED registration to discharge from observation) is at least 6 hours

Payment for extended emergency evaluation and management services should be limited to cases that require significant additional resources beyond those associated with an emergency department visit. To prevent abuse associated with keeping the patient in observation beyond the period of time that is medically necessary, a single payment rate should be applied, regardless of the total duration of observation. We recommend the following:

- Limit payment to cases that require at least six hours of care, measured from the time of ED registration to discharge from observation. This would apply whether these six hours were all used as an emergency service, or part of the time was spent as an emergency service and part as an observation service. Typically an emergency department visit for an admitted patient will last three to four hours. Using a six hour minimum adds a two to three hour “safety margin” to prevent over utilization of this service and avoid payment for cases that resolve quickly. This does not mean that ED encounters are routinely expected to last six hours. Encounters of this length or greater would qualify for incremental payment for extended emergency evaluation and management services requiring additional nursing and facility expenditures. This would provide payment of care for patients whose management needs fall into the

window of between 6 and 24 hours of care. This definition could be applied to any hospital, with or without a formal observation unit and without forcing a change in the patient's registration status from ED to observation or short stay admission.

5. Assign the new HCPCS to a new APC.

Payment for extended emergency evaluation and management services should be made in addition to the payment for the emergency department APC in recognition of the added costs for the services. We recommend the following:

- Create a new APC titled Extended Emergency Evaluation and Management Services

6. Do not limit payment to certain clinical conditions

In the final rule, HCFA states: *"During our first review of the APC groups, we will assess whether patients with certain conditions use observation services that should be separately recognized. Thus, correct diagnosis coding is required."* While we agree with the importance of correct diagnosis coding, we oppose limiting payment for this service to only a few specific conditions for the following reasons:

- The abuses of observation services in other settings will be solved with the restrictions listed above. Creating a restrictive list adds little more to these solutions.
- Restricting emergency services to specific conditions conflicts with the "prudent layperson" standard of defining an emergency based on presenting symptoms, not final diagnoses.
- Emergency observation services have been shown to be effective for a large number of commonly observed conditions. However there are countless other less common conditions that do very well in this setting and should not be excluded. Thus a "list of observable conditions" would either be so restrictive that it would not reflect reasonable medical practice, or it would be so large as to be problematic.
- Maintaining a restrictive list will be slow and unlikely to keep up with medical progress. Medical progress in this area has shifted care from the inpatient setting to an observation unit. Given the rate of medical progress it is likely that these transitions could be stalled by a restrictive list.
- A restrictive list would fail to cover all patients whose service needs fall into the 6 to 24 hour period.

Changes to the system must be made promptly

The new payment system will go into effect on August 1, 2000. As we understand it, there is no means of making the changes we recommend in time for an August 1, 2000 implementation date. In light of the concerns we have raised, we urge you to reconsider this position. At a minimum, it is essential that changes be made in conjunction with the first quarterly update.

We ask that HCFA reconsider its plans to wait for further claims data before making any changes in the current policy. The agency must recognize that if it appears that observation services will not be adequately covered, then asking hospitals to provide unfunded care while HCFA studies the losses incurred will dramatically bias practice behavior toward admission. This will skew the proposed cost data analysis. Additionally, because of the historically slow rulemaking process demonstrated by the outpatient PPS project, a large portion of U.S. observation units will close

before all data is collected and analyzed. Subsequently this data will be applied to a changed health care environment for which it is no longer representative.

By statute, the payment rates are based on the median costs of the services in the APC. HCFA should select from the 1996 claims file those bills that include charges for both emergency department services and observation services and compare them to bills for emergency department services alone. This should allow for the determination of the marginal costs of observation services without waiting for future claims data.

Proposed payment rate

We recognize that problems in the 1996 bill data may preclude the determination of an appropriate payment rate for extended emergency evaluation and management services. If that occurs, we recommend the assignment of a payment of \$375 based on our estimates of the cost.

Our cost estimates are based upon the ACEP observation sections' national survey, the VHA observation unit benchmarking study, and the experience of the ACEP observation section leaders who have toured emergency observation units around the country. As a general rule, we do not believe that payment for extended emergency evaluation and management services should exceed the payment for an inpatient day, which we estimate to be roughly \$600. The key determinants of costs are staff, space, support services and time. Each of these elements is described below:

- Nursing staff - Observation units typically staff with a nurse to patient ratio that is between that of a regular med-surg floor and a step down unit. The ratio is generally one nurse to somewhere between four and eight patients. The average is 1:5.
- Support staff - As unit volume increases, added support staff might be needed. On average one clerk and one tech will be needed for 15 to 20 patients. This is comparable to an inpatient med-surg unit.
- Space – Observation rooms are usually about 10 X 10 feet in size. The costs of maintaining this space in a hospital are associated as well.
- Support services – Observation patients need support services (such as food, linens, administrative costs, etc.) similar to inpatient med-surg units. Room and space needs to be amortized.
- Time - On average, patients in an observation unit require services for 15 hours, not 24 hours. Patients who fail or succeed do so, on average, within this time frame. This is time from arrival in the observation unit, to discharge from the unit. This time is consistent with a sampling of dedicated units, as well as the ACEP observation sections' recent national survey of emergency departments with dedicated observation units, and the VHA benchmarking survey of dedicated ED observation units.

A reasonable estimate of reimbursement for these services can be obtained by comparing these services to inpatient services. A detailed estimate would perhaps require a large-scale controlled study. This is not currently feasible, and may not be needed. In the absence of such a study, a reasonable best estimate is a good place to start. Modifications may be made over time as accurately coded data is collected in the future.

If we assume that 24 hours of inpatient care costs \$600, then 15 hours of observation would cost \$375. This is a conservative estimate of observation costs since observation units actually staff at a higher level than a traditional med-surg floor.

Conclusion


HCFA's decision to package payment for all observation services into other APCs will jeopardize patient safety and quality care and increase total Medicare costs. The policy fails to recognize the increased costs of emergency observation services and unless appropriate changes are made, access to medically necessary emergency observation care by Medicare beneficiaries will be seriously compromised.

Forcing emergency departments to provide up to 24 hours of uncompensated care will increase the financial burden and gridlock in emergency departments. HCFA's policy will only further weaken the nations' primary health care safety net, the emergency department. The current packaging of observation services creates an untenable position for hospitals and physicians. On the one hand, sending patients home too early will certainly lead to poor health outcomes. On the other, admitting them for inpatient care will drive up costs and decrease patient satisfaction.

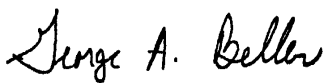
We have proposed a policy that HCFA could readily implement. The policy will overcome all of the problems associated with the recently announced policy, while eliminating the potential for abuse identified by HCFA in the final rule.

All of our organizations appreciate the opportunity to offer these comments and we look forward to continuing to work cooperatively with HCFA in order to address this important issue. We ask that necessary and appropriate changes be made as soon as possible in order to ensure that patients are not put at risk.

Sincerely,



Michael T. Rapp, MD, FACEP
President



American College of Emergency Physicians
George A. Beller, MD
President
American College of Cardiology



Lynn A. Smaha, MD, PhD
President
American Heart Association

/s/

James E. Udelson, MD
President
American Society of Nuclear Cardiology

/s/

Raymond D. Bahr, MD
President
Society of Chest Pain Centers and Providers

/s/

Bob Doherty
Senior Vice President
Government Affairs and Public Policy
American College of Physicians-American Society of Internal Medicine

Enclosure

Background Paper
Payment of Extended Emergency Evaluation and Management Services Under The
Outpatient Prospective Payment System Final Rule

I. Introduction

In the emergency department (ED), chest pain is common, accounting for 5% to 6% of visits to EDs. It is the symptom commonly associated with fatal cardiovascular diseases. This is the leading cause of mortality in the United States accounting for 42% of all deaths (1). According to the latest statistics released by the American Heart Association, approximately 1.25 million patients suffer an Acute Myocardial Infarction (AMI) each year and AMI deaths total 218,229 (1). Nearly 80% of patients with AMI present to the ED. Unfortunately between 2 and 8 percent of patients with AMI are inadvertently discharged home (2-13). This is because roughly one out of 20 patients with AMI are not at all “typical” in their presentation. It has been shown that patients with AMI who are discharged home experience twice the death rate (25%) of those admitted (13-14). Failure to diagnose and treat AMI has consistently accounted for the greatest total dollar loss for malpractice claims against emergency physicians (14-16).

To address these issues, many emergency departments are using observation units for extended evaluation of chest pain patients (sometimes called a chest pain unit) (17-20).

HCFA’s comment in final rule: “We assume that chest pain patients, such as those described by the commenters, are sent to the CCU or ICU for observation. We believe that, in general, if a patient needs to be monitored in the ICU or CCU for any length of time, then that patient should be admitted as an inpatient. Furthermore, we have never considered care furnished in an ICU or CCU to be outpatient services. Existing cost reporting instructions allow for the use of these specialty beds during a shortage of regular inpatient beds, but charges are to reflect routine care, not intensive care.”

This is a misstatement that most chest pain patients who would require observation “are sent to the CCU or ICU for observation”. There has been a fundamental change in health care delivery for chest pain patients with respect to the use of CCUs and ICUs in the last decade. Historically the CCU was developed over 30 years ago to care for patients with acute myocardial infarction and its associated complications. Over time CCUs became filled with patients at low to intermediate risk for myocardial infarction, most of whom did not have serious disease. Attempts to expedite inpatient care were repeatedly met with failure, with average inpatient stays of 2 to 3 days under the best circumstance.

It has been found that these patients can be managed at least as effectively, at greater than half the cost, and in roughly 12 to 18 hours in a chest pain observation unit setting (3). This has been shown in many studies including a number which were government funded (AHCPR – see attachment A) studies. Over time this approach has been embraced and encouraged by health care providers and payers. Recent studies have shown that roughly 22% of metropolitan emergency departments have a specific type of observation unit called a “Chest Pain Center” (17). It is estimated that a much greater percentage (27% to 40%) have a general Emergency Department Observation Unit. A move back in time to having these patients “sent to the CCU or ICU” will increase health care costs, increase missed heart attacks, and decrease patient satisfaction.

II. Clinical Issues

A. Observation of emergency department patients has been extensively studied and shown to provide improved health care outcomes.

Figure 1: Observation leads to a ten fold decrease in the error rate for “missed myocardial infarction” (the rate at which heart attack patients are inappropriately sent home) (3, 21-23). Preventable deaths and complications are avoided. Such improvement in quality of patient care has become a national focus since the Institute of Medicine's report on medical errors (24). A payment rule that inhibits observation will jeopardize the enhanced quality of patient care that is a benefit of observation services.

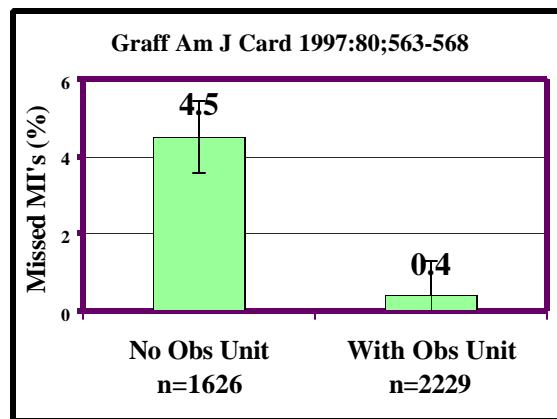


Table 1: Cost savings with avoided hospital admissions is also a benefit of observation. Multiple studies have shown charge and cost savings with the use of observation rather than hospital admission to evaluate patients with chest pain (25).

<u>Author/Year/reference</u>	<u>Savings/ pt</u>	<u>Study Design</u>	<u>Costing method</u>
Kerns/1993/26	\$1,873	Contemporaneous	Charges
Hoekstra/1994/27	\$1,160	Contemporaneous	Charges
Hoekstra/1994/27	\$2,030	Contemporaneous	Charges
Rodriguez/1994/28	\$1,564	Contemporaneous	Charges (mean IP)
Stome/1999/29	\$1,497	Contemporaneous	Costing
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Gomez/1996/32	\$624	Randomized	charges
Gaspoz/1994/33	\$698	Contemporaneous	costs (detailed)
Roberts/1997/34	\$567	Randomized	costs (detailed)

B. The 2 to 3-hour emergency department evaluation and treatment is not adequate for correct disposition of many patients.

Figure 2: The majority of patients with acute MI do not have a positive test upon evaluation in the emergency department (35-36). Thus physicians cannot rely upon initial test results alone. They must either admit patients to the hospital for a “rule out MI” evaluation when there is a suspicion

of acute MI, or send the low risk patient home. This figure shows the sensitivity of blood tests (CK-MB) or ECG over time in the diagnosis of acute MI.

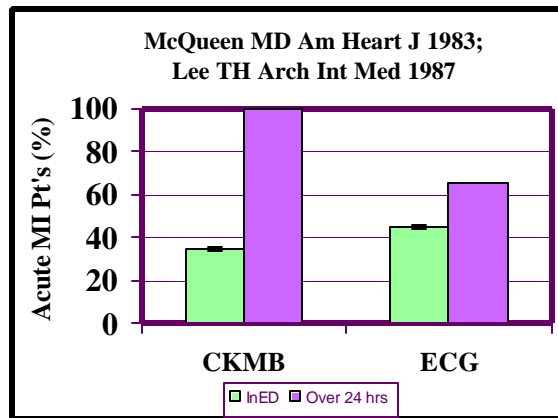
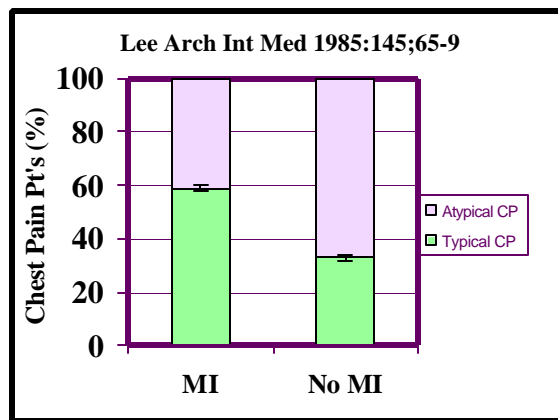
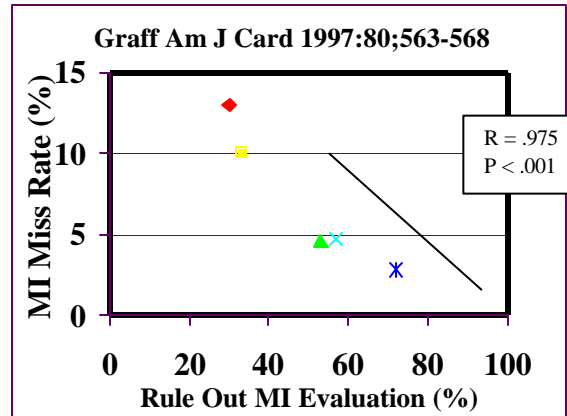


Figure 3: Many chest pain patients with acute MI do not have typical clinical findings of acute MI. Nearly half of admitted chest pain patients without acute MI have a history or other initial findings which may be 'classic' for acute MI. Thus in an “admit or discharge” system the physician must admit patients to the hospital who do not always have typical features of MI, in order to avoid inadvertently sending more MI patients home. (37).



C. Most ED chest pain patients need extended evaluation with observation or hospital admission to identify those acute MI patients who present with atypical signs and symptoms of their disease.

Figure 4: Acute MI patients with atypical presentations are identified during the extended evaluation with repeated blood tests, ECG monitoring, and physician reevaluation. There is an inverse relationship between the proportion of chest pain patients who receive a complete evaluation (admitted) and the rate at which AMI is missed (3).



Various factors affect the physician's threshold for hospital admission decision and thus the MI miss rate:

- Experience of the physician – more experienced physicians admit more patients and miss less disease (8)
- Risk attitudes of the physician – physicians with low risk personalities admit more patients and miss less disease (10)
- Hospital monitored bed capacity – physicians admit more patients when the hospital has high capacity for monitored beds and thus miss less disease (38-39)
- Clinical presentation – physicians are more likely to admit patients with typical presentations than atypical presentations and thus less likely to miss disease in the patient with typical signs and symptoms. Unfortunately atypical presentations for acute MI are not uncommon. (40)

D. Increasing the percent of ED chest pain patients admitted to the hospital for an extended evaluation, rather being released home from the ED, increases the overall costs (\$2764/patient vs. \$403/patient average cost).

Figure 5: There is a direct relationship between the proportion of chest pain patients who receive a complete evaluation (admitted) and the average cost per patient for chest pain patients (assumptions: \$403 average cost per patient ED evaluation, \$2764 average cost per patient hospital admission) (3).

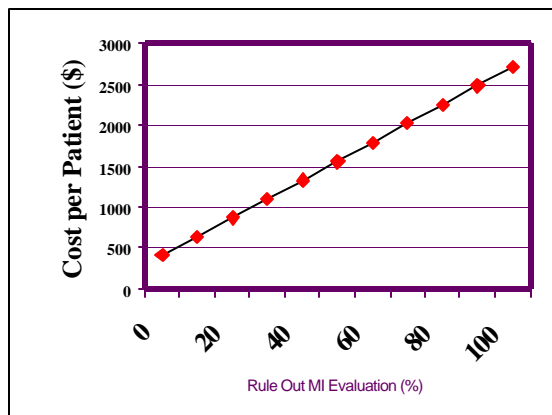
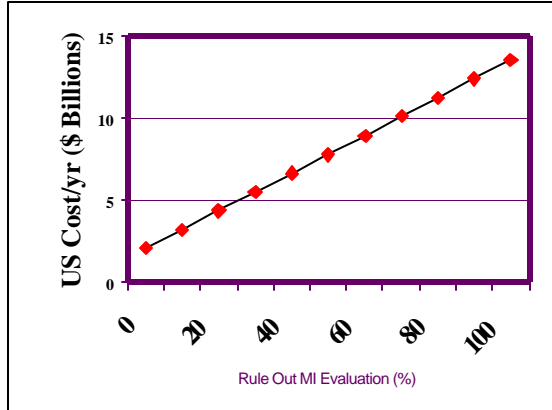


Figure 6: In an “admit or discharge” system, the total costs directly increase as the physician tries to improve quality of patient care by increasing the proportion of patients admitted. The total costs per year are the average cost per patient times 5 million chest pain patients per year evaluated and managed in US emergency departments (assumptions: \$403 average cost per patient ED evaluation, \$2764 average cost per patient hospital admission) (3).

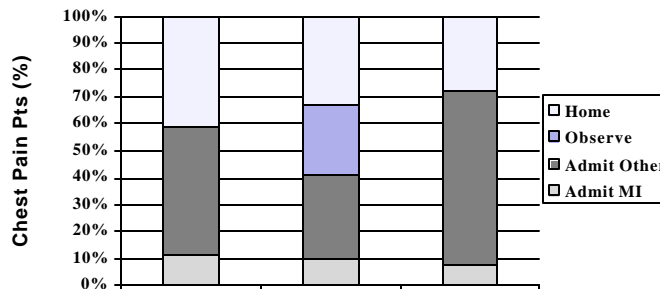


E. For the “traditional” ED chest pain patient disposition pattern (i.e. admit or discharge), 50% to 80% of admitted patients will not be found to have a serious disease. By hindsight their hospitalization was unnecessary (3, 5, 8).

Figure 7: Physicians make hospital admission decisions based on the “risk” of the potential disease and the “probability” that the patient has this condition (19, 41). With a condition like chest pain, patients are admitted to the hospital who are considered at risk of having an acute MI (high to moderate probability of disease) and the rest are released home. The physician faces a conundrum that the higher the admission rate, the fewer patients with serious disease miss but the higher the cost (14).

On average 60% to 70% of ED chest pain patients are admitted to the hospital even though only 10% of ED chest pain patients have an acute MI and 10% unstable angina (3, 5, 8). Patients are released home who clinically appear unlikely to have an acute MI (low probability of acute MI).

Puleo. N Engl J Med 1994;331:561-566. Graff Am J Card 1997;80:563-568.
 Pope. N Engl J Med 2000: 342; 1163-70.



Puelo n=1110 Graff n=2926 Pope n=10689

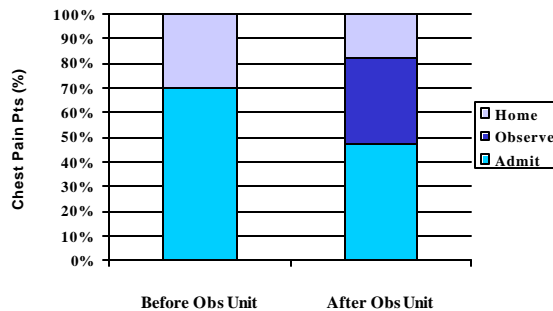
Unfortunately this traditional practice results in 3-5% of patients with acute MI being inadvertently released home.

III. Cost Issues

A. Observation improves utilization as well as quality of patient care.

Figure 8: With observation, a portion of patients who would have been admitted are 'ruled out' for acute MI and avoid unnecessary hospital admission (improved utilization). Also with observation a portion of chest pain patients with atypical clinical findings are 'ruled out for acute MI' rather than released home after the ED evaluation. Thus, more acute MI patients with atypical presentations are identified (improved quality of care) without as many unnecessary hospital admissions (improved utilization of resources) (30).

Mikhail M, et al. Ann Emerg Med 1997



B. Crucial to the success of the observation approach is the use of focused, accelerated protocols to provide services over 12 to 16 hours that traditionally were provided on an inpatient basis over 2 to 3 days.

Figure 9: In contrast to admitted chest pain patients, the costs for services to observed chest pain patients (called Accelerated Diagnostic Protocol in the study below) is bimodal. The majority of chest pain patients are released home after observation without hospitalization and have very low costs compared to hospitalized chest pain patients. A minority (20%) of chest pain patients are admitted after observation and their costs are similar to chest pain patients admitted after the ED evaluation (34).

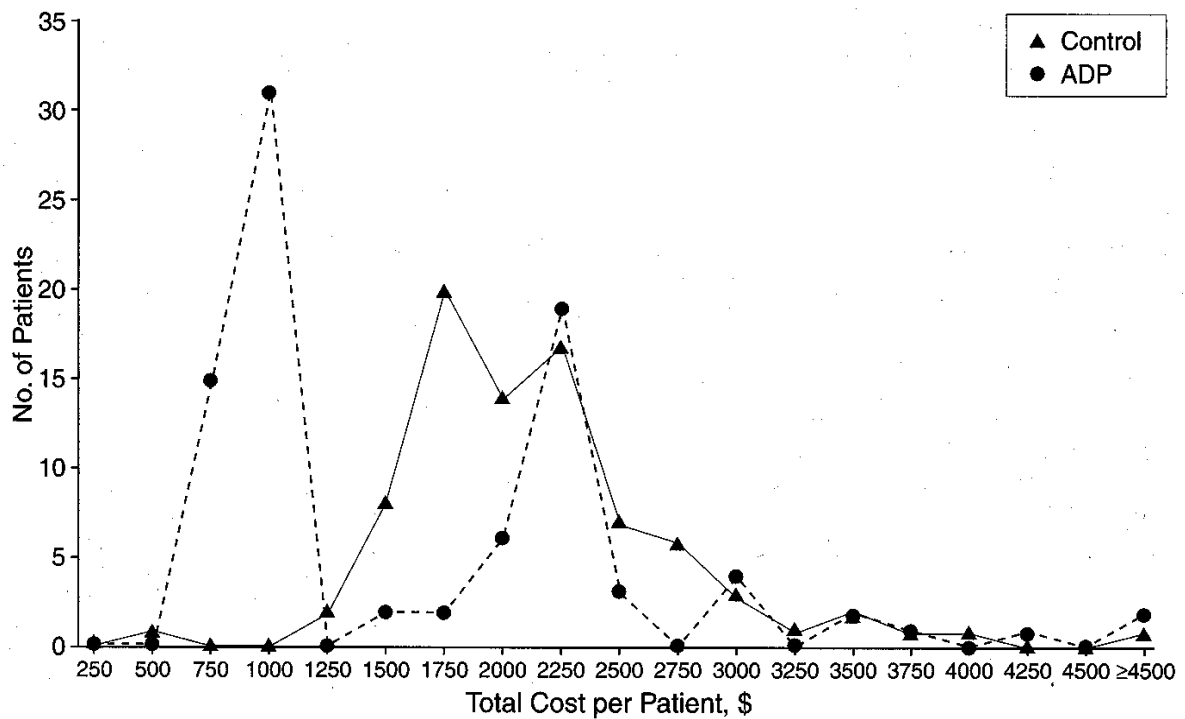


Figure 3.—Frequency distribution of total cost per patient. ADP indicates accelerated diagnostic protocol.

C. Emergency department observation units evaluate and manage a broad range of clinical conditions with focused, accelerated protocols over 12 to 16 hours rather than the 2 to 3 day inpatient stay.

Table 2: Chest pain comprises only 10% to 15% of patients who benefit from ED observation units. The range of conditions evaluated and treated in observation units is broad and includes the full range of conditions found in emergency departments (42-44).

Category	Conditions Observed
Evaluation of Critical Diagnostic Syndromes	Abdominal pain, chest pain, confusion, dizziness, edema, fever, gastrointestinal hemorrhage, headache, seizure, shortness of breath, syncope, toxicology/overdose, trauma, vaginal bleeding, weakness
Treatment of Emergent Conditions	Asthma, congestive heart failure, dehydration, hyper/hypoglycemia, infections, pain management/back pain
Meet Psychosocial Problems and Needs	Alcohol abuse, psychiatric problems, social problems

Avoiding hospital admissions on patients with chief complaints other than chest pain by use of a period of observation has similarly been shown to have great cost savings. Since 5% to 10% of ED patients are appropriate for observation, the cost savings in the United States (100 million emergency department visits per year) runs into the billions of dollars.

Table 3: Cost savings realized when Emergency Department based observation is used for various conditions.

Condition	ref	“Cost” Saving per Case*	“Charge” Saving per Case**	National Saving Potential
Chest pain	45	\$1330	\$2703	\$0.25-0.5 billion
Infections	46-47	\$1025	\$2050**	\$1 billion
Heart failure	48-49	<i>\$1174*</i>	\$2348	\$5 billion
Asthma	50	\$1045	\$2090**	Published estimate not available
Pneumothorax	51	<i>\$2122*</i>	\$4244	Published estimate not available
Upper GI bleeding	52	\$2943	\$5886**	Published estimate not available

*When published data not available, estimated at ½ of charges (noted in *italics*).

**When published data not available, estimated at twice cost savings (noted in *italics*).

D. Observation services have been shown to lead to an overall improvement in patient satisfaction:

Observation units have consistently been shown to provide better satisfaction and quality of life when compared with in hospital setting (53-54).

Table 2.
Satisfaction outcomes for entire study population.

Variable	CPOU (n=52) [Mean±SD]	Inpatient (n=52) [Mean±SD]	t	P*	95% CI	
					CPOU	Inpatient
Quality of service	3.25±.68	2.98±.61	2.12	.036	3.06-3.44	2.81-3.15
Receipt of desired service	3.38±.75	3.12±.73	1.86	.066	3.18-3.58	2.92-3.32
Fulfillment of hospital needs	3.37±.69	3.21±.57	1.24	.217	3.18-3.56	3.05-3.37
Recommendation of service	3.67±.55	3.08±.62	5.17	0	3.52-3.82	2.91-3.25
Satisfaction with service	3.40±.87	3.09±.72	1.96	.052	3.16-3.64	2.89-3.29
Effective handling of problem	2.63±.53	3.20±.56	4.07	0	3.49-3.77	3.04-3.36
Overall satisfaction	3.57±.64	3.06±.75	3.71	0	3.39-3.75	2.86-3.26

Scale ranges from 1 (lowest, strongly disagree, most dissatisfied) to 4 (highest, strongly agree, most satisfied)
*P values are for the Student t test or Wilcoxon rank-sum test.

While patient satisfaction and quality of life may not have clear monetary value when considering payment policy, it is clear that eliminating all observation services will worsen patient satisfaction (53-54).

Table 3.
Problems with care processes for entire study population.

Variable	CPOU (n=52) [Mean±SD]	Inpatient (n=52) [Mean±SD]	t	P*	95% CI	
					CPOU	Inpatient
Total problems	26.90±8.96	44.56±10.85	3.89	.0002	34.43–39.37	41.58–47.54
Communication	5.31±1.41	6.82±1.85	4.64	.0001	4.94–5.68	6.31–7.33
Special needs/preferences	5.33±1.08	5.90±1.14	2.58	.0113	5.04–5.62	5.59–6.21
Financial information	1.86±.76	1.49±.96	2.14	.0350	1.64–2.08	1.22–1.76
Emotional support	6.37±1.21	6.03±.89	1.57	.01181	6.04–6.70	5.78–6.28
Physical comfort	1.76±.92	3.43±1.51	6.70	.0001	1.51–2.10	3.02–3.84
Patient education	5.80±1.60	6.02±1.45	.72	.4735	5.35–6.25	5.61–6.43
Family involvement	3.31±2.26	3.06±1.25	1.02	.3120	3.00–3.62	2.71–3.41
Pain management	1.38±.95	1.50±1.15	.42	.6771	1.09–1.67	.99–2.01
Discharge preparation	12.21±5.40	13.04±4.17	.64	.5255	10.00–12.42	11.79–14.29
Perceived length of stay†	2.85±1.18	2.76±.77	.32	.7481	2.48–3.22	2.54–2.98

Generally scores ranged from low to high, with higher scores indicating greater numbers of adverse events for each cluster and for all problems with care processes combined.
 *P-values are for the Student t test or Wilcoxon rank-sum test.
 †Ranges from 1 (substantially shorter than needed) to 3 (about right) to 5 (substantially longer than needed).

IV. Inappropriate grouping of observation services: Appropriate and successful emergency department “Observation services” have been inappropriately grouped with other very different services.

A. Clarification of terms

“Observation services”, as recognized by HCFA, may take place in several different health care settings. It is worth clarifying certain terms and issues first:

- Postoperative or post procedure observation: One example is after scheduled “procedures” such as surgery or chemotherapy. These are scheduled and elective outpatients who are kept beyond the recovery period allowed for their procedure because of unexpected complications.
- Emergency department observation unit: A designated area within and under the direction of the emergency department for patients who require further treatment or evaluation to determine the need for admission.
- Chest pain observation unit: An observation unit that specifically focuses on chest pain patients.
- An "observation status bed", or 23-hour admit: A bed in the inpatient area of the hospital in which a patient may be evaluated or treated for up to 24 hours before a decision about disposition is needed. It is basically an insurance designation which makes a patient occupying an inpatient bed have an outpatient insurance designation for up to 24 hours.
- Holding unit: A designated area in the outpatient setting that may or may not be under the control of the ED in which a patient is held pending prearranged actions such as admission or transfer. A holding unit is often a manifestation of hospital inefficiencies and overcrowding. Observation services do not apply here.

B. History and APCs

HCFA's comment in final rule:

- *“Routinely billing an observation stay for patients recovering from outpatient surgery is not allowed under current Medicare rules nor will it be allowed under the hospital outpatient PPS. As we state in section III.C.5 of this preamble, one of the primary factors we considered as an indicator for the "inpatient only" designation is the need for at least 24 hours of postoperative care.”*

- *“After 1983, many hospitals began to rely heavily on the use of observation services when peer review organizations questioned admissions under the hospital inpatient prospective payment system. However, in some cases, patients were kept in “outpatient” observation for days or even weeks at a time.”*

We understand and appreciate concerns expressed by HCFA regarding abuses of observation in the post-operative and inpatient settings. However, observation of emergency department patients over the time frame of 6 to 24 hours is a well-established practice that preceded the introduction of the DRG in America. In fact it occurs in countries with emergency departments throughout the world - independent of a DRG based system. Recognizing these inherent flaws of observation services in other settings has driven this area of patient care to dedicated units, often in the emergency department setting. It is here that observation services, as defined by HCFA, can be provided most reliably.

Traditionally emergency services cover a period of 2 to 4 hours. Average inpatient admissions are roughly 5 days, with hospitals often experiencing payment denials for admissions of one day or less. Observation services meet the need of the patient group whose service needs range from 6 to 24 hours. The all or none, “admit or discharge” system does not cover these patients adequately.

Observation medicine, as it is developing in America, is a diagnostic tool where focused aggressive diagnostic testing or treatment is repeated over a specific timeframe to identify a patient's need for inpatient admission. The primary intervention employed is time. It has been better studied and proven than many more expensive technical innovations for which HCFA has decided to provide specific reimbursement.

C. Critical distinctions

HCFA's comment in final rule: – *“However, the cost data upon which the APC system is based contain all costs for observation in 1996, including those that exceeded the 48-hour limit imposed at the end of that year. We have packaged those costs into the service with which they were furnished in the base year. Thus, APC payments for emergency room visits include the costs of observation within the payment.”*

The 1996 data combines three very different services, (post-operative, inpatient observation status, and a dedicated observation unit) into one payment category. This is a critical point. The data does not differentiate between clinical services that have been shown to be successful and those that have been problematic for HCFA. Furthermore, it is not clear if patients observed in an inpatient bed had their costs assigned to the emergency department APC. It is not known how compliant emergency departments with observation units were in using the 762 billing code for emergency department observation services in 1996. In 1996 the new observation / hospital and same date discharge codes (99234-6) did not exist.

Observation units for emergency department patients – The undifferentiated nature of emergency department patients best fits the original description and intent of “observation services” set forth by HCFA. Emergency department patients present with a variety of symptoms such as chest pain or abdominal pain that may represent serious conditions, or illnesses such as infection, asthma, or congestive heart failure that require further treatment.

Post operative distinction – Emergency department and chest pain observation units do not generally “observe” post-operative patients. Observation of patients after an emergency department visit is distinctly different from post procedure observation services. These patients

present with undifferentiated symptoms that require further testing or acute conditions that require further treatment. Unlike post-procedure patients, emergency department patients represent unscheduled visits.

Inpatient observation status - Unlike inpatient observation status, it would be virtually impossible to keep a patient in an emergency department observation or chest pain unit for “several days to weeks” at a time. Because of the design of emergency department or chest pain observation units, many of the inefficiencies in rapidly managing observation patients in traditional inpatient beds are overcome.

V. Disincentives: the current APC cost structure appears to be a disincentive to the use of observation services, and does not appear to cover the actual costs of providing this service.

A. Current APC rule creates a disincentive to provide observation services:

HCFA's comment in final rule: “Although, as noted above, we received many comments urging that observation services be covered as a separate APC, we continue to believe that these services have been used so inappropriately in the past that we will have to gather data under the PPS before considering constructing a separate APC. We have packaged observation wherever it was billed.”

By providing separate APCs for other diagnostic and therapeutic services, but not for observation services, the perception is that this is not a recognized or reimbursed service. The comments made by HCFA regarding observation services demonstrate a strong bias against observation services. Claiming that it is combined with other APCs will not encourage its use, and make it very difficult for hospitals to track reimbursement for observation services provided. This creates a disincentive to observe and jeopardizes observation services. If this service cannot be clearly covered, many units will close. The alternative will be used, which is inpatient admission. It has been shown that when this group of patients is managed in a traditional inpatient setting length of stay and costs are greater. This will increase overall costs for Medicare. If this service is not adequately covered, then HCFA is essentially penalizing physicians and hospitals for attempting to provide high quality, cost-effective health care when the opportunity arises. Without separate revenue, observation units will not be able to operate and progress made in this area of medicine over the last ten years will suffer greatly.

HCFA's comment in final rule: “Further analyses will be necessary on the use of observation as an adjunct to emergency treatment, as in the case of chest pain. In order to ensure that we will have sufficient data for our future analyses, hospitals must continue to bill for observation using revenue center 762 and showing hours in the units field. Observation that is billed must represent some level of active monitoring by medical personnel. It must not be billed as a way to capture room and board for outpatients. During our first review of the APC groups, we will assess whether patients with certain conditions use observation services that should be separately recognized. Thus, correct diagnosis coding is required.”

If it appears that observation services will not be adequately covered, than asking hospitals to provide unfunded care while HCFA studies the losses incurred will dramatically bias practice behavior toward admission. This will skew the proposed cost data analysis. Additionally, because of the slow rulemaking process, a large portion of U.S. observation units will close before all data is collected and analyzed. Subsequently this data will be applied to a changed health care environment for which it is no longer representative.

B. Cost issues:

For hospitals there is a separate cost for providing observation services that is greater than the cost of the emergency department visit. Traditional emergency services only involve the immediate care of acutely ill and injured patients, then admission or discharge within 2 to 4 hours. Traditionally these patients would have been admitted and used inpatient resources. As pointed out above, observation services displace patient care from the inpatient setting to an outpatient setting with an overall decrease in cost for the patient visit. However this accelerated care over an additional 10 to 15 hours represents a significant increase in service and cost that is taken on by the emergency department.

The added hospital costs for observation services come in the form of additional nursing, clerical, and support staff for services provided as well as construction and maintenance costs. Observation units typically staff with a ratio of one nurse per 4 to 8 patients. As the number of patients increase, additional clerical and support staff become necessary. This staffing ratio ranges between that of a regular medical-surgical floor and that of an intensive care step down unit. These staff would not be added were these patients to simply have been admitted. For proper operation, observation rooms usually require 100 to 150 square feet of floor space with support equipment. As the number of rooms increase a central nursing station is needed. Again, these are costs that would not have been incurred if inpatient admission were chosen. We would be happy to work with HCFA in studying these costs to assure fair reimbursement.

C. Payment under an inpatient DRG vs. an outpatient APC

HCFA's comment in final rule: *“We assume that chest pain patients, such as those described by the commenters, are sent to the CCU or ICU for observation. We believe that, in general, if a patient needs to be monitored in the ICU or CCU for any length of time, then that patient should be admitted as an inpatient.”*

Using an inpatient DRG to pay for this group of patients may be problematic for two reasons. First, as has been shown above, if patients are admitted to an inpatient bed this may increase costs for HCFA. Second, many other third party payers (including HCFA carriers) are using increasingly stringent admission criteria (such as “Interqual”), which refuse inpatient admissions yet allow observation. If HCFA is then refusing to provide reimbursement for observation services it is creating a growing void into which patients will fall. It creates a large, and growing, patient population who are too sick to go home but not sick enough to be admitted. Forcing emergency departments to provide up to 24 hours of uncompensated care will create an enormous financial burden, and gridlock in emergency departments. This will only further weaken the nations’ primary health care safety net, the emergency department. On the other hand discharge will certainly lead to poor health outcomes. The current APC creates an untenable position where hospitals and physicians will be faced with selecting one poor outcome or the other.

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