



**American Hospital
Association**

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August 28, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1404-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates (Vol. 73, No. 139), July 18, 2008.

Dear Mr. Weems:

On behalf of the American Hospital Association (AHA) and our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year 2009 outpatient prospective payment system (PPS).

In the attached document, we provide detailed comments on several proposals. Specifically, we have serious concerns about the requirements for outpatient quality measure reporting, the proposed changes to hospital cost reporting for drugs, the payment rates for separately payable drugs, and the partial hospitalization program (PHP) payment reductions. In brief, we make the following recommendations:

- We strongly urge CMS to reconsider several aspects of its outpatient PPS quality reporting program. Most importantly, because the four additional measures of medical imaging efficiency that CMS proposes for hospital public reporting were still in the early stages of the National Quality Forum (NQF) process when the proposed rule was released, and because CMS did not provide sufficient detailed information about these measures in the proposed rule, it is impossible for the public to give appropriate and thorough comment. We believe that CMS has not fulfilled its administrative responsibility to provide adequate notice and opportunity for meaningful public comment on these measures.



These measures have not been endorsed by the NQF, nor adopted by the Hospital Quality Alliance (HQA). We strongly believe that measures added to the outpatient reporting program must first go through the rigorous, consensus-based assessment processes of both the NQF and HQA. At best, the measures may receive NQF endorsement by October 31, one day before the outpatient PPS final rule is expected to be published. They will not be considered by the HQA for adoption before they receive NQF endorsement.

- We are pleased with the process CMS has proposed for validating hospitals' outpatient quality data and believe it holds promise as a reasonable approach to ensure the accuracy of the quality data and serves as an improvement over the inpatient program validation process.
- We oppose CMS' proposal to create two cost centers for drugs because it would create an unnecessary burden for hospitals, require significant changes to accounting and billing systems and add costs related to hospital compliance – without adequate demonstration by CMS that these changes will lead to improved payment accuracy. We are concerned that CMS continues to expand and complicate the cost report, an antiquated data collection instrument. We urge CMS to engage with the field in a reasonable effort to design a current, accurate and useful tool that supports today's cost report uses.
- We are concerned that CMS' proposed payment rate for separately covered outpatient drugs, at average sales price (ASP) plus 4 percent, does not adequately represent the acquisition cost of outpatient drugs and their related overhead costs, as Congress intended. CMS' payment methodology has been shown in a number of recent analyses to contain serious flaws, which leads us to conclude that this methodology should be revised. Instead, we recommend that CMS pay for separately covered outpatient drugs at the rate at which they are paid in physician offices, currently ASP plus 6 percent. The law permits CMS to use this payment rate as an alternative.
- We support CMS' proposal to pay for PHP services using two new ambulatory payment classifications – one for days in which four or more services are provided and one for days in which three units of service are provided. However, in order to ensure continued beneficiary access to the more intensive level of PHP services provided in hospitals, we recommend that CMS use only hospital-based PHP data to determine the rates at which PHP services will be paid. Hospital-based PHP data are reliable, predictable and national in scope.

Thank you again for the opportunity to comment. Our detailed comments are attached. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Attachments

**The American Hospital Association's
Detailed Comments on the Proposed Rule
for the 2009 Outpatient Prospective Payment System**

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OUTPATIENT PPS: QUALITY DATA

Reporting of Hospital Quality Data

The Tax Relief and Health Care Act of 2006 mandated that the Centers for Medicare & Medicaid Services (CMS) establish a program under which hospitals must report data on the quality of hospital outpatient care to receive the full annual update to the outpatient prospective payment system (PPS) payment rate. A hospital that fails to report data will incur a reduction in its annual payment update factor of 2.0 percentage points, beginning in January 2009.

Quality Measures for 2009. To implement this legislative mandate, CMS required hospitals to begin reporting on seven initial measures of surgical care and care for heart attack patients who are transferred beginning on April 1 in order to receive their full payment update for 2009. As we commented in last year's proposed rulemaking, we are concerned that the measures implemented for 2009 have never been fully field-tested for their use for hospital outpatient reporting. Thus, we remain concerned that the data that are collected and reported will not present an "apples to apples" comparison of quality.

Although hospitals are just beginning to collect data for these measures, we have heard concerns that the measures are not specified in such a way as to allow hospitals to unambiguously identify the relevant patient population and collect the data accordingly. For example, the procedure codes used by hospitals to identify services in the outpatient setting often have modifier codes attached that designate a unique circumstance for a particular patient. One of the commonly used modifiers reflects those instances when a patient's surgical procedure is cancelled. Sometimes the patient comes to the hospital for surgery and begins pre-operative procedures but, before the surgery commences, it is cancelled, because the patient's vital signs are not stable. In these instances, the hospital submits a modifier on its Medicare bill to reflect that the surgery was not completed. According to the current specifications, hospitals are not allowed to submit any modifier codes when defining their applicable patient populations. Thus, patients whose surgeries are cancelled are classified by CMS into the surgical measures' denominator population even though hospitals likely, and appropriately, did not give the patient the prophylactic antibiotics. In reporting on these measures, hospitals that do not include these patients in their population would be considered non-compliant because they did not include all of their surgical patients, yet hospitals that do include these patients may have lower performance rates because the patients did not, and should not have, received antibiotics. If the measures had been field tested, this flaw in the specifications and others would have been identified and could have been corrected.

We urge CMS to provide funding immediately to fully field test the surgical care and heart attack transfer patient care outpatient measures to identify operational issues and assess the degree to which these measures can be corrected before data validation on these measures commences.

Quality Measures for 2010. **We strongly believe that all measures added to the outpatient reporting program should first go through the rigorous, consensus-based assessment processes of both the NQF and the HQA.** CMS proposes four additional measures of medical imaging efficiency that it would require hospitals to publicly report to receive the full payment update for 2010. We are extremely disappointed that CMS has chosen to propose these measures, which have not been endorsed by the National Quality Forum (NQF) nor adopted by the Hospital Quality Alliance (HQA), for 2010 payment purposes.

It is too soon to consider these measures for implementation. Because the measures were still in the early stages of the NQF process when the proposed rule was released, there was no information available to the public on the detailed specifications of the measures. These measures were developed by CMS alone, and, as of the publication of the proposed rule, CMS was the only entity with knowledge of how the measures are specified. The only information presented in the proposed rule on which the public could comment was the title of the measures. The titles alone, however, do not provide sufficient information on what process or outcome is being measured, what patient population is eligible or what scientific evidence underlies CMS' belief that the measurement will address a critical aspect of quality. In other words, the public did not have access to the information needed to fully understand what was being proposed.

Under the *Administrative Procedure Act* (APA), CMS is required to provide in its proposed rules all relevant information for any measures it intends to use, including the structure of the measure, the applicable patient population and any other facts used by the agency to inform its decision to propose the measure. In the past, CMS has proposed measures for the reporting programs that have not completed the NQF endorsement process, and for which detailed information on the measures was not contained in the proposed rules. Nevertheless, in other instances the proposed measures were either in the final stages of the NQF endorsement process, so that detailed information on the measures was widely available to the public, or already in use for another reporting program, such as The Joint Commission core measures or the Agency for Healthcare Research and Quality patient safety indicators. Thus, while past proposed rules did not themselves contain detailed information on the measures, there was information available in the public domain that individuals and organizations could reference to understand the measures in order to enable those interested to provide CMS with informed comments on any proposed measures. For these imaging efficiency measures, however, no information existed in the public domain at the time CMS released the proposed rule.

Because no information was otherwise available, and CMS did not provide more detailed specification of these measures in the proposed rule itself, it is impossible for the public to give appropriate and thorough comment. CMS has not fulfilled its responsibility under the APA and Medicare statute to provide adequate notice of and an opportunity for meaningful public comment on these measures. These measures should not have been proposed for 2010 and should be tabled until the NQF has fully evaluated and endorsed the measures; CMS has conducted robust field testing of the measures; the HQA has considered whether they are important and appropriate measures to include in the public report card on

hospital quality known as *Hospital Compare*; and the public has been provided notice of the measures in a manner that permits informed comment on their merits.

All measures adopted for public reporting need to be properly field-tested to ensure that the data can be collected reliably and that the measures tell a meaningful story about hospital performance. For example, the proposed billing data to be used for the imaging measures would include Medicare patients only. By excluding all other patients, there is the potential that the measures could distort the true picture of the delivery of imaging services.

Further, data derived from administrative sources, such as billing data, need to be tested against the information derived from medical records. Administrative data do not have the clinical richness that medical records data have, and, therefore, biases can be introduced into the measures. The comparison is necessary to answer the question, “Does this measure derived from administrative data provide a picture of quality that is reasonably accurate?” Given the information we have available, it appears that this testing has yet to be performed. To do thorough testing on the validity of the measures, CMS should undertake a study that identifies hospitals with varying levels of results on the imaging measure calculations and examine more closely, using chart abstraction and structured interviews, the provision of care in those facilities. Such a study would allow the agency to understand how care differs among hospitals and whether the number-crunching of the claims data reflected the true picture of care at each facility.

Four weeks into the public comment period on this rule, the NQF published the information needed to understand and appropriately review these measures; however, the NQF’s process is not a substitute for CMS’ obligation to publish information in its proposed rules. While the NQF’s publication puts information in the public domain, it is unclear whether all interested parties who typically rely on the *Federal Register* as the authoritative source for the information they need to review and comment on proposed federal rules would know to look at the NQF’s Web site for additional information. Nothing in the *Federal Register* notice or on CMS’ Web site pointed to this source of information. Further, the NQF process provides only 28 days for members and 21 days for non-members to comment – a far shorter period than anticipated in the APA as being available to the public to comment on public rules.

From the NQF materials, we know that only two of the four proposed measures, magnetic resonance imaging (MRI) of the lumbar spine and use of contrast for thorax computed tomography (CT), are likely to receive NQF endorsement. Our review of the NQF materials suggests that none of the proposed measures is appropriate for implementation in the outpatient reporting program at this time. Our specific comments on the measures are included below.

- *Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain*. This measure assesses the percentage of patients who had an MRI of the lumbar spine for a diagnosis of low back pain without evidence from their medical claims that they received conservative therapy before receiving the MRI. We do not believe that this measure is ready for

implementation, and, even with further testing and improvement, it is more suitable for physicians than hospital outpatient departments.

Specifically, we are concerned that the measure assesses the utilization of imaging services by the rendering facility and not by the ordering practitioner. The measure is more applicable to physicians who order the imaging tests than to the hospital outpatient departments where patients go to fulfill their physicians' orders. Hospitals have little control over the ordering practices of community physicians or have access to a patient's community-based physician medical records to know what diagnostic tests or treatments the patient has received prior to arrival at the hospital for an MRI. It also is unclear as to what steps hospitals should take to improve their performance on this measure. We do not believe that CMS would intend for hospitals to refuse access to MRIs for certain patients without prior therapy; however, implementation of this measure could have unintended consequences for patients' access to services.

This measure has not been thoroughly tested to determine whether it is an appropriate indicator of efficient care or whether it can provide meaningful information to both hospitals and the public. CMS pilot-tested the measure, but included only one hospital outpatient department in that testing. The agency calculated hospitals' preliminary measure rates using Medicare claims but was unable to include patients with other insurance coverage. Thus, the preliminary rates may not reflect the true picture of care provided by hospitals. In its calculation of the claims data, CMS found low variability in the measure rate among providers. Therefore, it is unclear to what extent the measure will show any differences among hospitals. Information that does not distinguish among providers is unhelpful to consumers attempting to use the information for health care decision-making, and to providers who wish to use it for quality improvement purposes.

- *Use of Contrast: Thorax Computed Tomography (CT)*. This measure assesses the use of combined studies of CT scans of the thorax, both with and without contrast material, to assess for the appropriate use of CT scans. We do not believe that this measure should be implemented at this time. CMS' preliminary calculations of the measure found a relatively low use of combined studies. In the Medicare claims analysis, only 8 percent of hospital outpatient department CT scans were conducted as a combined study. If this measure were framed in a manner comparable to the other, existing clinical process measures, this would translate to a 92 percent national average performance rate, even before the measure was implemented. Thus, it is unclear to what extent there is room for improvement on this measure.
- *Use of Contrast: Abdomen CT*. This measure assesses the percentage of abdomen CT scans performed with the use of contrast material for certain patients. This measure should not be implemented as it is currently defined. There is a lack of evidence in the published literature to determine the appropriate use of contrast for these patients. Without evidence that tells what the appropriate number of combined studies should be, providers will be unable to evaluate their own performance against a best practice, and

the public will find it difficult to interpret the results. Further, the measure contains a number of patient exclusions, and the applicable patient population is unclear.

- *Mammography Follow-up Rates.* This measure assesses the recall rate of an imaging facility providing mammography services. This measure is not ready for implementation. Similar to our concerns regarding the abdomen CT measure, there is a lack of consensus as to what the appropriate recall rate should be, thus it is unclear what rate hospitals should be striving to achieve. In addition, there is no established link between providers' recall rates and patient outcomes. Because patient population characteristics vary among hospitals, this measure should be risk-adjusted to reflect these baseline differences. We are concerned that inappropriate application of this measure could result in unintended consequences for patients. A focus by providers on lowering the rate of follow-up diagnostic testing could decrease access to these tests and lead to an increase in the number of undiagnosed early cancers.

Quality Measures for Future Years. In the proposed rule, CMS lists 18 additional measures that it may consider for implementation in the outpatient reporting program for 2011 or later and seeks comments on the appropriateness of these measures. Without further information, the AHA cannot comment on the substance or appropriateness of these measures. However, some of the measures, such as management following a bone fracture and low density lipoprotein control in diabetes patients, seem more relevant to a physician office environment than a hospital outpatient department.

Proposed Process for Updating Measures. CMS proposes to establish a sub-regulatory process to update the technical specifications used to calculate the measures when scientific or consensus standards change. **The AHA is strongly opposed to this idea. All changes to existing measures should be made through the regulatory process, which allows for public comment.** We understand that, at times, it may be necessary to temporarily suspend measure reporting due to a change in science or an implementation issue, such as when past influenza vaccine shortages have affected the inpatient reporting program. **However, all permanent revisions of existing measures must be made through the regulatory process to allow for public input.**

We are pleased that CMS agreed with this approach in the fiscal year (FY) 2009 inpatient PPS final rule (*CMS-1390-F*) and decided not to adopt a sub-regulatory process to make modifications to the inpatient reporting program measures. We urge the agency to confirm in the outpatient PPS final rule that it intends to suggest changes to the outpatient measures only through the regulatory process.

Reporting for Low-volume Hospitals. Beginning in 2010, hospitals with five or fewer patients for a quality measure in a calendar quarter would not be required to submit data on that measure or related measures for that calendar quarter. For example, if a hospital has five or fewer patients eligible for one of the heart attack transfer measures, the hospital will not have to report data for any of the five heart attack transfer measures for that quarter. The AHA supports this

approach as a sensible way to reduce the reporting burden on hospitals with a very small number of cases; however, we believe that hospitals should always be able to voluntarily report on quality measures if they wish.

We are concerned that these hospitals will have to submit their patient population counts to CMS each quarter. Hospitals are beginning to collect their aggregate Medicare and non-Medicare patient population counts for submission for the inpatient reporting program, and we are hearing from hospitals that determining this information is burdensome and time-consuming. The challenges are great for both larger hospitals with very large patient populations and smaller hospitals with less integrated health information technology systems. In addition, we have heard that the identification of the patient populations for the outpatient measures is proving to be even more challenging. We are concerned that implementing a low-volume policy will do little to reduce hospitals' burden if they still must undertake tremendous effort to prove that they indeed had only a small number of applicable patients. Hospitals that may never report quality data would still have to establish a mechanism to identify their patient populations every quarter.

While we agree with the concept of reducing the burden for hospitals with small patient caseloads, we urge CMS to rethink the implementation mechanism. There are several alternative methods that could be used. For example, CMS could base the low-volume determination on its analysis of hospitals' Medicare claims. Alternatively, CMS could use QualityNet data to determine which hospitals have submitted data for a very low number of patients in 2008 and then deem those hospitals low-volume hospitals. Finally, the low-volume determination should be done on an annual rather than a quarterly basis. If a hospital has a very low number of cases in one quarter, that low-volume determination should hold for a year. Some hospitals will be on the cusp of having five eligible cases; they may have five cases in one quarter, six in the next and four cases in the following quarter. It will be challenging for these hospitals to know how to allocate resources when they may have to ramp up and then scale back their quality reporting efforts. Allowing these hospitals to plan for a year at a time will alleviate these resource challenges.

Data Validation. CMS proposes a new process for validating hospitals' outpatient quality data. Unlike the process for the inpatient reporting program, which involves the review of a small number of medical charts from all hospitals, the proposed process would audit a larger number of charts from a randomly selected sample of hospitals. Beginning with services delivered on January 1, CMS proposes to review 50 medical charts from 800 randomly selected hospitals each year. The review would assess the accuracy of each hospital's measure rate, as opposed to the accuracy of the individual data elements. **The AHA believes that CMS' proposed process holds promise as a reasonable approach to ensure the accuracy of the quality data and improve upon the deficiencies in the inpatient program validation process.**

We urge CMS to ensure that the selection process is truly random and not biased so that any particular group of hospitals is likely to get selected more frequently. We believe that it is appropriate to focus on the hospital's measure rate, as opposed to individual data elements, because the measure rate captures the information that is truly important to patient care. For data

validation in the inpatient reporting program, there have been several instances in which a mismatch between single data elements unrelated to the quality of care provided by a hospital, such as the patient's birth date, have caused hospitals to fail validation. Validating the hospital's measure rate should eliminate these unfortunate incidents.

The burden to hospitals will be reduced if they do not have to submit records for validation every year. However, because hospitals will be selected at random each year, there is no guarantee that a hospital selected in one year will not be selected in the following year. We urge CMS to refine the validation selection process so that hospitals selected for validation in one year are not eligible for selection again until two years later. Alternatively, CMS could ensure that no hospital is selected more than two times within a five-year period. This will help ensure that a particular hospital is not disproportionately burdened by the selection process. Additionally, CMS should consider allowing hospitals that pass validation with a very high score to receive a "pass" from the validation process for several years. Such a policy will encourage hospitals to ensure that their data are as accurate as possible and reward those hospitals with high accuracy rates. Again, we are generally pleased with CMS' proposal for the outpatient quality data validation process, and we urge the agency to continue to refine the plan put forward in the proposed rule. We also urge CMS to implement a similar validation program for the inpatient reporting program.

Currently, when hospitals receive their validation results from the inpatient reporting program, they receive a summary report that informs them of any errors that were made in their data submission. This has been very valuable to hospitals, and they use the information in the summary reports to improve on their data collection and reporting to avoid making future mistakes. We urge CMS to produce these reports for hospitals for the outpatient reporting program data validation. In particular, given the lack of quality improvement organization involvement with the outpatient reporting program, these reports will provide some much-needed technical assistance to hospitals.

To pass validation, CMS proposes that hospitals meet a minimum of 80 percent reliability from chart validation. We believe that this is too stringent a requirement in the first year of data validation. We urge CMS to set a lower threshold for validation for the 2009 outpatient data. After the first year, it may be appropriate to raise the validation threshold if an examination of the outpatient reporting program shows that the measures are well-specified and hospitals can reliably collect the data.

We agree with CMS' proposal not to publicly report outpatient quality data that has not been validated. Although it is disappointing that data will not be available to the public until 2010, we believe it is of the utmost importance that the accuracy of any data used for public reporting be verified before posting. We also urge CMS to post the hospital outpatient reporting data on the *Hospital Compare* Web site to provide the public with one central source for hospital quality information.

For those hospitals that fail to meet the outpatient reporting program requirements, CMS proposes to implement for 2010 a reconsideration and appeals process similar to the one used for the inpatient quality reporting program. We believe that such a process is a vitally important component of the outpatient reporting program. CMS should establish a reconsideration process that is straightforward, transparent and timely. Hospitals should have clear guidance on how to submit their appeals, and CMS should expedite its appeals decisions.

CAHs and ASCs: Quality Data Reporting

Although they have no Medicare financial incentives to participate in the inpatient quality reporting program, many critical access hospitals (CAHs) voluntarily choose to do so. CAHs participate in the quality reporting program because of their commitment to public transparency and quality improvement. The outpatient measures adopted by CMS last year, the heart attack transfer measures and the surgical care measures are particularly relevant to CAHs and the patients they serve. The heart attack measures were specifically developed as part of the work undertaken to identify measures relevant to rural providers. They are most relevant for small hospitals that tend to stabilize and transfer the majority of patients with heart attack symptoms who present at their emergency departments. The surgical care measures are derived from the work of the Surgical Care Improvement Project and are appropriate for any location in which common surgeries are performed.

In the first year of the outpatient reporting program, CMS did not allow CAHs to voluntarily submit quality data. Although CMS stated that CAHs would be able to participate in the future, the agency has yet to publish formal notification of its intent, and no concrete timeline has been provided. **The AHA strongly urges CMS to allow CAHs to voluntarily report on the outpatient quality measures as soon as possible, and to publish a formal written notice of when they may begin to do so.** The 2009 outpatient PPS proposed rule would have been an excellent vehicle to convey this information.

The Tax Relief and Health Care Act of 2006 mandated that the Secretary include ambulatory surgical centers (ASCs) in the outpatient quality reporting program. In the 2008 outpatient PPS/ASC final rule, CMS stated its intent to implement quality reporting for ASCs in a future year. In the 2009 outpatient PPS/ASC proposed rule, CMS again delays implementing quality reporting for ASCs. **The AHA encourages CMS to implement a quality reporting system for ASCs as soon as possible.** All providers that perform the same services should be held to the same accountability standards with respect to the quality of the care they deliver. Likewise, patients deserve the same transparency about the quality of care from all facilities where they may seek a particular service. It is unfair that patients have access to surgical quality information from hospital outpatient departments, yet that same level of transparency is unavailable from ASCs.

HEALTHCARE-ASSOCIATED CONDITIONS

CMS is seeking comment on whether and how the Medicare inpatient PPS policy of not paying more for preventable healthcare-associated conditions could be applied to the hospital outpatient department setting. Because making such changes to the outpatient PPS would require congressional action, CMS does not propose new Medicare policy at this time. Rather, the agency is seeking public comment on options and considerations for potential future application.

The AHA urges caution against expanding the healthcare-associated conditions policy to any other settings or providers until CMS has the opportunity to analyze the effects of implementing the policy in the inpatient hospital setting. In particular, an examination of any unintended consequences and the potential for increased and unnecessary diagnostic testing should be conducted.

CMS will need to consider other technical challenges to implementing a healthcare-associated conditions policy in hospital outpatient departments due to the infrastructure differences between outpatient departments and inpatient facilities. For example, many of the laboratory tests necessary to identify present on admission status for certain conditions could not be completed within the short timeframe that a patient is in the outpatient department. In the outpatient setting, payment is based on the types of services provided and not on the severity of the patient's illness, as it is in the inpatient setting. Thus, the payment policy in place for healthcare-associated conditions in the inpatient setting is not applicable to payment in the outpatient department.

Before developing any plan for expanding this program, **we recommend that CMS develop an advisory panel of clinicians and scientists to provide the agency with guidance in developing the policy.** The advisory panel should include both academic researchers and clinicians who are actively providing patient care in the outpatient hospital setting.

CHARGE COMPRESSION AND RECOMMENDATIONS FOR IMPROVING ACCOUNTING

In the proposed rule, CMS addresses concerns about potential bias in the outpatient PPS cost-based weights due to "charge compression," which can potentially lead to undervaluing high-cost items and overvaluing low-cost items in the calculation of cost-based ambulatory payment classification (APC) weights. CMS commissioned the Research Triangle Institute (RTI) to explore this issue and proposes to adopt or support several of their accounting recommendations, including:

- Creating additional standard cost centers on the cost report for drugs with high overhead costs and drugs with low overhead costs and instructing hospitals to use revenue code 0636 for drugs with high overhead costs;
- Adding fixed descriptions to the cost report software;
- Clarifying instructions requiring hospitals to report all standard cost centers if they offer services of the appropriate type; and

- Conducting educational initiatives on reporting capital costs.

CMS seeks comments on RTI's other recommendations, particularly their suggested revisions to the revenue code-to-cost center crosswalk and recommended creation of standard cost centers for CT scanning, MRI and cardiac catheterization. CMS has elected not to propose RTI's recommended statistical adjustments to the cost-to-charge ratios (CCRs), choosing instead to focus on steps to improve the quality of cost report data. The AHA's responses to these proposals are discussed below.

Divide Cost Center 5600 into Two Cost Centers

The AHA opposes CMS' proposal to create two cost centers for drugs. We believe that this proposal would create an unnecessary burden for hospitals, require significant changes to accounting and billing systems and add costs related to hospital compliance. CMS has not adequately demonstrated that these changes will lead to improved payment accuracy. We believe that the change to the handling of medical devices and supplies addressed the most significant area of charge compression and no further adjustments are supported by the data.

Furthermore, we remain concerned that CMS continues to expand and complicate the antiquated Medicare cost report rather than make a reasonable effort to design a current, accurate and useful tool. The current uses of the Medicare cost report were never intended. The continued "piecemeal" approach to modifying the cost report is costly and burdensome. We urge CMS to partner with the hospital industry to consider more comprehensive changes to the cost report.

Regardless of whether CMS accepts our recommendations, we strongly urge the agency to provide adequate notice before it implements any changes to the cost report – hospitals will need sufficient time to make potentially significant changes to their billing and accounting systems well in advance of the start of their fiscal year. While the AHA applauds CMS' decision to push back the effective date of the revised cost report until spring 2009, this still may not provide sufficient time for implementation.

The AHA also has concerns about the options that CMS proposes for capturing the cost of drugs with high overhead costs.

- *Option 1: Use of Revenue Code 0636.* CMS proposes using revenue code 0636 to capture high overhead drug costs as the least burdensome approach for hospitals. While we agree that this would be the least burdensome option of those described, this approach only works if revenue code 0636 captures a preponderance of drugs with high overhead costs. Currently, this revenue code includes a mix of high and low overhead drugs. Changing the definition of this code would require approval from the National Uniform Billing Committee. Failure to do so would potentially corrupt the integrity of the uniform billing and payment system. If this code were to be redefined, such change would require modifications to hospital billing systems and payer payment systems.

Additionally, a number of Medicaid programs are now requiring all drugs with HCPCS codes to be billed under revenue code 0636 so that the National Drug Code can be separately identified on the UB04 to meet new CMS requirements. This will result in a mix of high- and low-cost drugs under this revenue code.

- *Option 2: Use the Outpatient PPS Drug Packaging Threshold.* The AHA agrees that using the drug packaging threshold to differentiate drugs is unlikely to result in a meaningful separation of high- and low-cost overhead drugs. Furthermore, identification of overhead cost for every drug is complex, costly and time consuming.
- *Option 3: Establish a Cost Threshold – Require Hospitals to Identify the Cost of Pharmacy Overhead for Every Drug.* This approach would be the most complex and burdensome option for hospitals. It would require hospitals to identify the cost of overhead for every drug in order to determine if it should be placed in a high or low overhead cost center. The cost to implement this approach would greatly outweigh the benefit. In addition, an auditing process would be required to examine the accuracy of each classification creating an additional burden and cost for the hospital and auditing body.
- *Option 4: Base Separation on Overhead Categories Suggested in the 2006 Proposed Rule – Require Billing Consistent With Established Cost Categories.* The same concerns that the AHA expressed in 2006 are still relevant today. That is, this approach would require hospitals to charge Medicare a rate based upon the three categories to recognize the differences in overhead. However, hospitals would charge other payers differently if they do not recognize the three categories and have not agreed to the use of the existing revenue codes as suggested in the CMS proposed rule. This option would require modification to each hospital's billing system in order to accommodate Medicare. Other means would be needed to accommodate other payers. This approach would be extremely burdensome for hospitals. It is inconsistent with Medicare's requirement that providers maintain uniform charges for all payers. In addition, given the degree of variation among hospital "mark-up" policies, it is quite likely that all three categories would still contain a mixture of drugs with high and low overhead. Overall, the AHA believes that this approach is overly complex and will likely lead to inconsistent interpretations between the auditors and hospitals. The result is a burdensome and costly process for the hospital and auditing body.

Thus, we oppose CMS' proposal to create two separate cost centers for drugs. Each of the proposed options is excessively burdensome and fails to achieve the goal of better separating high and low overhead drugs. In addition, CMS has not adequately demonstrated that these changes will lead to improved payment accuracy.

We agree that the use of estimates to determine the separation of the drug cost center, through a regression-based approach as suggested by RTI, is inappropriate. Actual hospital data should be used to assure accuracy.

Finally, we believe that the change to the handling of medical devices and supplies addressed the most significant area of charge compression and no further adjustments are supported by the data. Should CMS wish to explore this issue further, it should be done in collaboration with the hospital field in the context of broader cost report reform.

Other Proposed Cost Report Changes

The AHA's comments on RTI's other recommendations follow.

Add Fixed Descriptions for Nonstandard Cost Centers to Cost Report Software. We agree that adding fixed descriptions of non-standard lines to the cost report software would provide improved clarification without increasing the reporting burden. Uniform descriptions should allow for better analysis of future data. Hospitals would still be able to enter a line description. We also suggest that CMS improve the cost reporting and/or vendor software instructions to clarify the specific cost centers that should be reported on nonstandard cost center lines.

Clarify Instructions that Require Hospitals to Report all Standard Cost Centers if They Offer Services of the Appropriate Type. Create Standardized Cost Centers for CT Scanning, MRI and Cardiac Catheterization. We have two concerns with the requirement for hospitals to report all standard cost centers for which they provide a service. These concerns also apply to the proposal to add the three new standard cost centers. First, the service must meet the CMS definition for reporting as a separate and distinct cost center. Adherence to CMS' criteria is essential for the service to be reported as a standard cost center. Second, we are concerned that some smaller hospitals may not have accounting systems that allow matching costs to revenues in all departments for which a standard cost center might be established. A particular service may be part of the responsibilities of a larger department and costs may be intermingled across functions. For example, a hospital may have a single therapy unit that provides physical, occupational and speech therapy. This unit may share supervisory and administrative staff, as well as space. Splitting these costs would be burdensome and could lead to new sources of inconsistency across hospitals.

Use Text Searches of Providers' Line Descriptions to More Appropriately Classify Nonstandard Cost Centers in Current Hospital Cost Report Data. We support CMS' use of text searches of line descriptions for classifying nonstandard cost centers. We believe that this would result in better data from already submitted cost reports.

Slightly Revise CMS' Cost Center Aggregation Table to Eliminate Duplicative or Misplaced Nonstandard Cost Centers and Add Nonstandard Cost Centers for Common Services Lacking One. We support CMS' efforts to improve the classification of nonstandard cost centers through elimination of duplicative and misplaced nonstandard cost centers and the addition of new nonstandard cost centers for common services. We agree that this effort would support greater uniformity and accuracy to help achieve more consistent cost-based weights. We would support these changes with the understanding that only those hospitals that have the ability to separate

the costs, charges and statistics related to these modified nonstandard cost centers would be required to utilize them.

Revise the Revenue Code-to-Cost Center Crosswalk. CMS specifically requests comments on the addition of “default” CCRs for clinic, cardiology and therapy services before defaulting to the overall ancillary CCR. However, we are uncertain as to how these “default” CCRs will specifically impact both the APC and diagnosis-related group cost-based weights. We request that CMS provide additional information identifying and comparing the cost-based weights under both the current and suggested approaches.

Create New Nonstandard Cost Centers for Services that are Well Represented in Line Descriptions Associated with “Other Ancillary Services” Cost Centers, Including Cardiac Rehabilitation, Hyperbaric Oxygen Therapy and Patient Education. We support CMS’ efforts to allow for more specificity in the reporting of cost centers in the cost report by providing for additional non-standard cost centers that will allow for more precise mappings within the outpatient PPS revenue crosswalk. We support these changes with the understanding that only those hospitals that have the ability to separate the costs, charges and statistics related to these new nonstandard cost centers be required to utilize them.

Use Direct Assignment of Equipment Depreciation and Lease Costs, as Opposed to Current Allocation Basis (Square Footage). We agree that the direct assignment of equipment depreciation and lease costs or the allocation of movable equipment based on dollar values of assigned depreciation costs will provide a more accurate allocation basis for capital equipment than square footage. Most hospitals, especially the larger hospitals, are likely to have this information available to include on the cost report. We urge CMS, however, to continue to allow small rural hospitals the option of utilizing the square footage statistic.

OUTPATIENT PPS: SPECIFIED COVERED OUTPATIENT DRUGS

The Medicare Modernization Act of 2003 provisions require special classification and payment of certain separately paid drugs, biologicals and radiopharmaceuticals that had previously (or before December 31, 2002) received pass-through payments. In 2009, the law requires that payment for these specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to adjustment for pharmacy overhead costs.

For 2009, CMS proposes to pay for the drug acquisition *and* pharmacy overhead costs of specified covered outpatient drugs at a *combined* rate of ASP plus 4 percent. To set the 2009 rates, CMS evaluated fourth quarter 2007 average sales price (ASP) data on drugs and mean costs derived from 2007 outpatient PPS claims data. It concluded that using mean unit cost to set the payment rates for the drugs and biologicals would be roughly equivalent to basing their payment rates at ASP plus 4 percent. The agency cites findings from a 2005 Medicare Payment Advisory Commission (MedPAC) study of pharmacy overhead costs to support its conclusion that ASP plus 4 percent is sufficient to cover drug acquisition and pharmacy overhead costs. The

MedPAC survey results indicated that hospitals set charge levels for drugs to cover both drug acquisition and pharmacy overhead costs.

The proposed rate for 2009 is lower than the ASP plus 6 percent rate for drugs furnished in physician offices and also lower than the ASP plus 5 percent rate paid in 2008. Lowering the payment percentage from 5 to 4 percent above ASP is a budget-neutral change to the outpatient PPS and redistributes the additional 1 percent of payments to other outpatient services.

The AHA believes that this rate is inadequate and recommends that CMS pay for separately covered outpatient drugs at the rate at which they are paid in physician offices – ASP plus 6 percent. Reducing payment for separately payable drugs under the outpatient PPS, while maintaining drug payments at ASP plus 6 percent for drugs provided in physician offices, creates inconsistencies in payment that could result in unintended and inappropriate incentives to treat patients in one setting versus another. CMS should eliminate the inconsistency of paying differently for the same drugs based on the treatment setting.

Further, the proposed reimbursement rate for drugs at ASP plus 4 percent is inadequate to cover acquisition cost, let alone pharmacy services and handling. A growing body of evidence shows that CMS' methodology for calculating payment for separately paid drugs is not adequately addressing problems in the claims data and is contrary to the statute, yet CMS proposes no immediate corrections. Instead, the changes to cost reports that CMS proposes would impose significant burdens on hospitals, and the agency and would affect payment no earlier than 2011.

The Social Security Act, at Section 1833(t)(14)(A), requires that CMS reimburse for these separately paid drugs at a rate that is equal to the average acquisition cost for the drug for a year, as determined by General Accounting Office (GAO) or CMS surveys of hospital acquisition cost. The law goes on to state, that if hospital acquisition cost data are not available, CMS is to pay at the rates applicable in physicians' offices – ASP plus 6 percent or the rates set under the Competitive Acquisition Program. The law, at Section 1833(t)(14)(E), also authorizes CMS to adjust payments for these drugs to pay for overhead and pharmacy service and handling costs.

However, CMS' current payment methodology is not consistent with this provision. That is, neither the GAO nor CMS have conducted surveys of hospital acquisition cost since 2004. And the methodology CMS currently uses is not a survey but rather an inaccurate extrapolation from claims data. Although CMS states that its methodology is the "best currently available proxy for average hospital acquisition cost and associated pharmacy overhead costs," several analyses, as mentioned below, show that CMS' methodology produces rates that do not represent hospital acquisition cost and pharmacy overhead.

CMS' methodology for calculating drug acquisition cost and pharmacy overhead has consistently fallen far below other studies that have attempted to estimate these costs. For instance, based on a 2004 survey, the GAO reported that actual drug acquisition costs, *not including overhead*, at ASP plus 3 percent for hospitals. MedPAC, in its June 2005 Report to Congress, reported that non-drug hospital pharmacy costs were roughly 26 percent to 28 percent

of total pharmacy costs. Most recently, CMS' own contractor, RTI International, found that CMS' methodology substantially underestimates the costs of acquiring and supplying separately paid drugs.

These findings suggest a fundamental methodological problem with CMS' analysis of hospital costs. A study by the Moran Group, on behalf of Centacor Inc., found that CMS' methodology consistently underestimates the costs of separately paid drugs and overestimates the costs of packaged drugs. These problems are caused by CMS dividing drugs into two groups, packaged and separately paid, but applying the same cost-to-charge ratio to both groups. Moran's analysis found that CMS' use of a single departmental average CCR to estimate costs results in understating the costs associated with separately paid drugs with the highest costs and overstating the costs associated with packaged lower cost drugs. These skewed cost estimates are what CMS uses to determine the overhead associated with the separately paid drugs. When The Moran Group replicated CMS' methodology (using 2006 claims and ASP data), but applied it to all drugs with HCPCS codes, regardless of their packaging status, it found the ASP equivalent rate to be ASP plus 12.6 percent – far higher than the ASP plus 3 percent that CMS estimated using only the separately payable drugs from the same year of data.

This finding suggests that, if CMS continues to use its current flawed methodology to calculate drug payments, as the packaging threshold increases over time, the rate that CMS calculates for separately payable drugs will continue to decline, conceivably to levels that fall below ASP. This result is unsustainable and clearly inconsistent with the intent of Congress.

Another problem with the CMS methodology is that it incorporates data from hospitals that receive 340B program discounts for drugs they purchase. The 340B program allows certain hospitals that serve poor and uninsured patients to purchase drugs at deeply discounted prices. When CMS compares its estimated mean unit costs to ASP to determine a payment rate for all hospitals, it includes hospitals that purchase drugs under the 340B program in its analysis, although the 340B sales are excluded from the ASP calculation. As a result, CMS underestimates the aggregate costs of drugs for most hospitals, and the ASP-based rate that CMS produces by comparing aggregate costs to ASP is too low.

A study by Christopher Hogan of Direct Research found that when the 340B hospitals are excluded from CMS's analysis, the mean unit cost rises to ASP plus 7.6 percent. While the 340B program was not intended to harm other hospitals' ability to provide care by reducing their Medicare reimbursement, this is another flaw in CMS' methodology. We believe this further supports our view that CMS should abandon its current approach and default to the other option provided by Congress – to pay for separately covered outpatient drugs at the rate at which they are paid in physician's offices, at ASP plus 6 percent (or the CAP rate, as applicable.)

PROPOSED OUTPATIENT PPS PAYMENT FOR DRUG ADMINISTRATION

In 2007 CMS implemented the full set of Current Procedural Terminology (CPT) drug administration codes including the concepts of initial, sequential and concurrent administration. Previously, these concepts had been reported using C-codes. For 2009, CMS proposes to continue using the drug administration CPT codes for outpatient PPS reporting.

The 2009 rate setting process is the first opportunity CMS has had to examine hospital claims data for the full set of CPT codes. As a result, for 2009 CMS proposes to reconfigure the drug administration APCs from six APCs to a five-level APC structure based on significant clinical and resource differences among services.

We believe that the coded data CMS is using to make APC changes are inadequate. Hospitals have had to learn and transition to the new codes, but there continue to remain areas where the definitions and guidelines for the assignment of drug administration codes are vague or vary by fiscal intermediary interpretation. The two most prominent areas for the lack of consistency are:

- *The administration of biological response modifiers.* Different opinions have been issued as to whether these drugs should be coded as administration of chemotherapy or as intravenous infusion for therapy.
- *Lack of documentation of stop time for infusions.* Some hospitals have had problems implementing the requirement for documentation of stop and start times for infusions that stop automatically. Some FIs have recommended that these infusions should not be reported or billed at all because of the lack of complete documentation, while others have allowed the reporting of a therapeutic injection. This results in incomplete and inconsistent data.

The AHA recommends that CMS delay reconfiguring the drug administration APCs from six APCs to a five-level APC structure until these issues are resolved and there are more stable and correct data upon which to base these decisions.

OUTPATIENT PPS: PARTIAL HOSPITALIZATION

For three years, CMS has expressed concern that the median per diem cost derived from hospital and community mental health center (CMHC) claims data was too low to cover the cost of partial hospitalization programs (PHPs) that typically should span four to six hours per day. However, CMS still implemented a 15 percent decrease in the per diem for 2006, another 5 percent decrease in 2007 and a 13 percent reduction in 2008, which resulted in a PHP per diem rate of \$203.

Proposed Payment Policy for 2009

In the 2008 and 2009 proposed rules, CMS considered the number of services being provided in a day of care as a possible explanation for the continued decline in the calculated per diem cost

for PHP. Updated claims data showed that, despite CMS' expectation that five or six services should be provided in a day, CMHC PHPs in 2007 had more low-intensity days – days in which three or fewer units of service were provided – than in the previous year. By contrast, hospital-based PHPs in 2007 reported fewer low-intensity days compared to 2006. Specifically, 28 percent of hospital-based PHP days contained three or fewer units of service and 73 percent CMHC PHP days contained three or fewer units of service. CMS indicates that it never intended PHP days with three services to represent the number of services that ought to be provided on a typical day. CMS expects that days with only three services would be provided in limited circumstances, such as when a patient is transitioning towards discharge.

For 2009, CMS proposes to create two separate APCs for PHPs – APC 0172 Level 1 Partial Hospitalization (three services) and APC 0173 Level 2 Partial Hospitalization (four or more services). This is consistent with our 2008 proposed rule comments in which we recommended that CMS consider differentiating payment based on the intensity of services provided during a day of PHP services. **We are pleased that CMS has followed through on our recommendation and support the creation of these two new APCs.**

Unfortunately, the proposed payment rates CMS calculates from combined CMHC and hospital-based PHP median cost data – \$140 for APC 0172 and \$174 for APC 0173 – represents another significant reduction in payments for PHP services, even for the new high-intensity APC that will be paid 14 percent less than the PHP rate in 2008. Yet another steep payment reduction for PHP services is untenable, particularly on top of the 33 percent reduction CMS has made since 2006. We predict that this will cause many hospitals to reconsider whether they can afford to continue providing these services and will force many PHPs out altogether, with a serious negative impact on patient access to PHP services.

In order to ensure continued beneficiary access to the more intensive level of PHP services typically provided in hospitals, we recommend that CMS use only hospital-based PHP data to determine the rates at which PHP services will be paid in hospital-based settings. Hospital-based PHP data are reliable, predictable and national in scope.

AHA and NAPHS Analysis of PHP Data

The AHA does not come to this conclusion lightly. Due to concerns that PHP rates have been falling precipitously over the last several years, the AHA together with the National Association of Psychiatric Health Systems (NAPHS) this spring contracted with The Wellington Group to conduct an analysis of three years of PHP data, including data from 2003, 2004 and 2006, in order to better understand the reason for the continuing decline in PHP median rates and provide insights for policy decisions. We have attached to this comment letter a description of the results of this analysis. The story that the data tell is compelling and directly leads to our recommendation that hospitals be paid for PHP services using only hospital-based data.

The data show that, while the aggregate number of PHP service providers has remained relatively stable over time, with only a 2 percent decline since 2003, the mix of PHP providers has shifted significantly. Between 2003 and 2006, the number of hospital-based PHPs has

dropped by 16 percent while the number of CMHC PHPs has increased by 53 percent. What is even more striking is that the majority of this growth in CMHC PHPs has occurred in only three states: Florida, Louisiana and Texas.

As the number of CMHC providers has grown, the volume of services they provide has increased dramatically. CMHC providers now account for a disproportionate share of the PHP days. Between 2003 and 2006, CMHC days increased a staggering 150 percent while hospital PHP days declined by nearly 6 percent.

We found that CMHC services are heavily concentrated in only a few states, while hospital-based PHP services are more national in scope. Six southern states account for 78 percent of CMHC providers, and CMHCs in Florida, Louisiana and Texas account for 74 percent of all PHP days nationally. In addition, 27 states do not have any CMHC PHPs, and only 30 percent of states have more than one CMHC. By contrast, hospital-based PHPs are more widely dispersed, with the top six states accounting for only 41 percent of hospital providers, and 80 percent of states have more than one hospital-based PHP program. However, the number of states without a hospital-based PHP is growing.

In addition, our analysis shows that, between 2003 and 2006, rural areas in particular experienced significant declines in the number of PHP providers, with a 47 percent decline for rural hospitals and a 33 percent decline in rural CMHCs. In fact, the only PHP provider category that has grown is urban CMHCs, which have experienced a 72 percent increase, with the same three dominant states – Florida, Louisiana and Texas – accounting for virtually all of this growth.

Our analysis also demonstrates that CMHC and hospital-based PHPs responded to reductions in the payment rates in different ways.

Between 2003 and 2006, as Medicare payment rates dropped, CMHCs responded by reducing their PHP service intensity. That is, CMHC PHP days with fewer than four services doubled from one-third to two-thirds, and days with five or more services fell to 11 percent, down from 30 percent. As reported in this year's proposed rule, this trend continued in 2007, with 75 percent of CMHC days having fewer than four services. At the same time, CMHCs dramatically increased their volume of services, with the number of days between 2003 and 2006 increasing 64 percent.

By contrast, hospitals' response to the reductions in payment rates was far more responsible, with hospitals remaining committed to the CMS vision of partial hospitalization as a high-intensity service. Days with four or more services remained stable at just over two-thirds of hospital days, while days with five or more services actually increased to 18 percent in 2006, up from 13 percent the previous year. The 2009 proposed rule reports that this trend continued in 2007, with 72 percent of hospital-based PHP days including four or more services.

In conclusion, our analysis shows that partial hospitalization is becoming regionalized as CMHCs in a few states dominate the provision of services and effectively set the rates for all

PHP services. We are concerned that, as payment rates decline, access to care will erode, particularly in rural areas. Partial hospitalization is a critically important service that is intended to be just a step below inpatient psychiatric services, and these economic incentives are undermining the ability of hospitals to continue to provide the appropriate clinical intensity of PHP services.

As noted earlier, **the AHA supports CMS' two-tier payment proposal, but we feel strongly that this concept does not go far enough to promote service intensity and continued access to these important services. As a result, we recommend that CMS use hospital data to establish PHP payment rates.** There are several reasons why this change in the payment methodology makes sense.

- *Payment for Hospital Outpatient Mental Health Services Capped at the PHP Rate.* There is a long-standing policy capping the aggregate payment for less intensive outpatient mental health services furnished on the same date at the payment for a day of partial hospitalization, which CMS considers to be the most intensive of all outpatient mental health treatment. Indeed, in the proposed rule, CMS states that it would pay for the Mental Health Services Composite APC 0034 at the same rate as the proposed APC 0173 (Level II Partial Hospitalization (4 or more services)). This means that CMHCs, providers not eligible to provide APC 0034 or other non-PHP hospital outpatient services, are having a negative effect on the payment rate for these hospital outpatient services. As a matter of principle, the AHA believes that hospital data should be used to set the payment rates for hospital services. We are concerned that continuing to use the combined PHP rate methodology will result in reduced access not only for hospital-based PHP services but also for other less intensive mental health services provided in hospital outpatient departments.
- *CMHC PHP Data are Unstable while Hospital-based PHP Data are Consistent and Reliable.* CMHC median costs have fluctuated wildly over time, from lows of \$140 to highs of \$1,000 per day. CMS also suspects that some CMHCs have been changing their charges so as to maximize outlier payments. While this has been addressed in recent years, it has resulted in outlier payments that also have fluctuated significantly. By contrast, hospital-based PHP median costs have been consistent and stable from the start of the outpatient PPS, ranging from \$200 to \$225 per day. In addition, hospital data are more reliable, as they are based on detailed and audited cost reports that are more sophisticated than the CMHC financial reporting system.
- *Hospital-based PHP Data are National in Scope while CMHC Data are Regional.* Forty-three states have at least one hospital-based PHP and 80 percent have two or more. In contrast, 78 percent of CMHCs are located in six southern states, with the heaviest concentration and growth in just three states – Florida, Louisiana and Texas.
- *Hospital-based PHPs are Meeting Statutory Intent and CMS Objectives for Partial Hospitalization Services.* Because partial hospitalization is provided in lieu of inpatient

care, CMS believes it should be a highly structured and clinically intensive program, usually lasting most of the day. Hospital-based programs live up to this vision with nearly three-quarters of hospital-based PHP days reporting four or more units of service. In fact, the hospital-based PHPs have increased the proportion of such high-intensity days over the past few years, despite declines in the payment rate. By contrast, CMHCs have been reducing the intensity of their services over the last several years and, therefore, have not been living up to CMS' expectations for PHP services. As mentioned, in 2007, nearly three-quarters of CMHC PHP days have three or fewer services.

- *Financial Impact and Concern about Further Rate Reductions.* While our recommendation will result in payment for PHP services in 2009 that are higher than what they would be if CMS finalized its proposed policy, we note that the overall expenditures for PHP services would still decline from the previous year. Further, the CMS proposed PHP rate of \$203 per day is about the same as that estimated by CMS for a high-intensity hospital-based PHP day (\$205). The AHA is concerned that any further reduction in rates will threaten access to PHP services in many states. Most states have only hospital-based PHPs, and closures of these programs will force more patients into inpatient care, which could cost the Medicare program even more.

CMS has already acknowledged many of the concerns that we raise herein, and we believe that the notion of using hospital-based PHP data exclusively to set the rate for these services is one that CMS has considered in the past. We urge the agency to use only hospital PHP data to set payment rates for hospital-based PHPs.

Other PHP Proposals for 2009

Proposal to Deny Payment for Low-intensity Days. CMS proposes to deny payment for any PHP claim for days when fewer than three therapeutic services are provided. CMS states that three services should be the minimum number of services allowed in a PHP day, and days with one or two services do not meet the statutory intent of a PHP program. **In general, the AHA supports CMS' proposal to deny payment for these "low unit" days. However, we believe that there may be legitimate circumstances that could justify the provision of only one or two units of PHP services in a day.** Two examples are if the patient suddenly becomes ill, or if a personal or family emergency requires that they cut their day short. In these very rare circumstances, we believe that CMS should pay, at a reduced level, for the services provided to the patient as long as there is a reasonable rationale provided in the patient's medical record. **Therefore, we recommend that CMS create a modifier that could be used in such rare circumstances and that would trigger a "suspension of claims for medical review" and payment at a reduced rate.**

Proposal to Strengthen PHP Patient Eligibility Criteria. In order to strengthen the integrity of the PHP benefit, CMS proposes putting into regulation its existing policy regarding PHP patient eligibility. These are requirements currently included in the *Medicare Benefit Policy Manual*, Publication 100-92, Chapter 6, section 70.3, and includes the requirement that, "Partial

hospitalization programs are intended for patients who—(1) Require 20 hours per week of therapeutic services.”

The AHA supports adding these patient eligibility criteria to the regulation and believes that this will reinforce the statutory intent for partial hospitalization to be a highly structured and clinically intensive program. However, we request that CMS clarify that it intends the first patient eligibility criterion to be applied only as a general patient eligibility guideline similar to the others added to the regulation and that it is *not* intended to be applied in an inflexible manner to deny coverage of services or payments for individual patients. We believe that, while a need for 20 hours per week of therapeutic services is a useful benchmark in general to help determine whether a patient is an appropriate candidate for partial hospitalization, the type and level of services provided to individual patients in a particular week of care should be a determination made by a physician and based on careful consideration of a variety of clinical and individual factors. For instance, frequently when patients step down to PHP from inpatient care, they attend five times per week for a week or two, then titrate down to three times per week, then two, and then are stepped down again to receive care in other outpatient mental health settings. It may be impossible to transition patients to lower levels of care effectively and still meet that 20-hour standard if the standard is treated in an inflexible manner.

A precedent for this approach is found in the inpatient rehabilitation facility PPS, which requires patients to receive “intensive therapy,” interpreted as three hours of therapy per day, five days a week. Known as the “three-hour rule,” this is a guideline that can fluctuate per day according to individual factors such as diagnosis, patient status and whether a patient can tolerate three hours of therapy on a given day. The quantity and type of therapy provided to inpatient rehabilitation patient, including any fluctuations, must be documented in the patient’s chart and provided in accordance with the physician’s plan of care.

OUTPATIENT PPS: HOSPITAL VISITS

Since April 2000, hospitals have been using the American Medical Association’s CPT evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that the E/M descriptors – designed to reflect the activities of physicians – did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services.

In 2003, the AHA and the American Health Information Management Association recommended hospital E/M visit guidelines based on the work of an independent expert panel comprised of representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience. Despite CMS’ previous assurances that it would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in

2007 the agency established new HCPCS level II G codes to distinguish visits provided by Type B EDs (not open 24 hours a day, seven days a week – 24/7).

Proposed Codes and Coding Policy for 2009

Since the publication of the 2008 outpatient PPS/ASC final rule with comment period, CMS examined the distribution of clinic and Type A ED visit levels based upon updated 2007 claims data available. CMS continues to observe a normal and stable distribution of clinic and ED visit levels in hospital claims.

Clinic Visits, New Versus Established. For 2008, CMS continued using CPT E/M codes for clinic visits including separate codes for new and established patients. The distinction between new versus established patients for hospital coding is based on whether the patient has had a medical record number assigned within the previous three years. During the past year, CMS heard from several provider groups that hospitals cannot easily distinguish between new and established patients for the purposes of correctly reporting clinic visits. However, CMS believes it is appropriate to continue to recognize the CPT codes for both new and established patient visits because hospital claims data continue to show significant cost differences between these visits.

Therefore, for 2009, CMS proposes to retain the distinction between “new” and “established” patients in its coding policy but modify the definitions as they apply to hospital outpatient visits based on whether or not the patient was registered as an inpatient or outpatient of the hospital within the past three years. **As in our comments to last year’s proposed rule, the AHA continues to recommend that CMS remove the distinction between new and established patient clinic visits.**

While current distinctions between new and established patients in the physician E/M codes exist, the same concepts do not apply to facility resources. From a physician’s perspective, an established patient may require a shorter history and a less comprehensive physical exam. These same economies are not necessarily factors in determining facility resource codes. For example, using CMS’ definition, a person may be an established patient at a facility because of previous visits to any number of outpatient settings, including the ED, a clinic, as an inpatient, for a diagnostic exam or for any other service. Previous services may or may not be related to the current visit, but it would be extremely difficult for facilities to have to determine whether there was a previous encounter and whether previous services performed were related to the current visit. This determination is especially difficult for medium-sized hospitals and nearly impossible for small hospitals. For these hospitals, in rural communities in particular, nearly every patient seen will have had some type of contact with the hospital.

The interventions performed during an encounter are determined by physician orders, but the actual performance of these interventions would be the same whether the patient was new or established. **The AHA believes that clinic visits should be recognized on the basis of hospital resources utilized during a specific visit and, therefore, not determined by whether the patient was registered as an inpatient or outpatient in the hospital within the past three**

years. Therefore, we continue to recommend that CMS eliminate this distinction between new and established patients.

ED Visits. In 2007, CMS introduced a distinction between two types of EDs and referred to them as Type A and Type B based primarily on whether or not the department was open 24 hours a day, seven days a week (24/7), and met one or both requirements related to the Emergency Medical Treatment and Labor Act definition of a dedicated ED. Type A EDs are open 24/7 while Type B EDs are open less than 24/7. For the last two years, in the absence of hospital claims data to evaluate the cost of services furnished in Type B EDs, CMS opted to pay for Type B ED visits at the hospital *clinic rate* rather than at the higher ED rates assigned to Type A ED visits.

CMS now has access to two years of Type A and Type B ED cost data on which to establish payment rates for 2009. Using these data, CMS indicates that most emergency visits to Type B EDs are more expensive than clinic visits, but less costly than emergency visits to Type A EDs. Therefore, for 2009, CMS proposes four new APCs for services provided in Type B EDs. According to CMS, the proposed payment rate for the new Type B APCs reflects these cost differences. However, as the costs for the most intensive emergency visits are approximately the same between Type A and B EDs, CMS proposes to use a single APC for these visits.

We continue to be concerned about CMS' definitions and payment structure for Type A and B ED visits. Specifically, the new policy implemented by CMS' 2007 final outpatient PPS rule led to significant confusion and concern about how hospital "fast track" areas are treated. Fast track areas generally function as a part of the ED that handle specialized cases (e.g., heart-related emergencies) or less emergent cases so that patient flow can be improved through a hospital ED. They can be physically adjacent to or even located within the 24/7 ED, but hospitals often discontinue triaging patients to fast tracks during certain hours (e.g., the midnight shift). Due to this confusion in how to treat fast tracks, hospitals and Medicare fiscal intermediaries have interpreted this policy in different ways, with some assigning services provided in fast tracks to Type A ED services and others to Type B.

The AHA has stated that paying for the services provided by these non-24/7 ED fast tracks as Type B ED services – at the clinic rate, as CMS did in 2007 and 2008 – does not make sense from a national policy perspective. ED overcrowding and ambulance diversions are significant issues for America's health care system and fast tracks improve patient care, patient flow and patient satisfaction. CMS' policy has led many hospitals to consider closing these special units, a move that would exacerbate the nation's ED diversion and overcrowding problems.

And while the proposed payment policy increasing the payment for Type B ED services for 2009 is an improvement, CMS' policy remains confusing and has led to different interpretations on the appropriate coding for fast track ED services. To help make matters clearer, the AHA once again recommends that CMS apply the following criteria:

If a hospital with a Type A 24/7 emergency department has a "fast track" area to which some patients are sent for expedited or specialized care, the fast track area is part of the Type A ED and can bill using the Type A ED CPT codes, regardless of the fast track's hours of operation, as long as:

- **The fast track is a hospital-based facility that provides unscheduled episodic services to patients who present for immediate medical attention;**
- **The fast track area is physically located within the same building as the 24/7 ED; and**
- **The 24/7 ED and the fast track share a common patient registration system.**

As noted, we believe that there are differences in the way fiscal intermediaries determine whether a hospital's fast track area should be considered a Type A or Type B ED. The fact that CMS claims data reflect that the costs for the most intensive emergency visits are approximately the same between Type A and Type B EDs implies that similar services are being provided by the two types of EDs at the higher visit levels. **The AHA recommends that CMS conduct further analysis of cost data to determine if the differences between Type A and Type B EDs continue to be reflected on a regional basis, or whether the differences are driven by potential differences in fiscal intermediary interpretations of the fast track ED area.**

Proposed Treatment of Guidelines for 2009

CMS proposes that until national guidelines are established, hospitals should continue to report visits according to their own internal hospital guidelines to determine the different levels of clinic and ED visits. In the proposed rule, CMS notes their continued expectation that hospitals' internal guidelines would comport with the principles listed in the 2008 outpatient PPS/ASC final rule. Hospitals with more specific questions related to the creation of internal guidelines are to contact their local fiscal intermediaries or Medicare Administrative Contractors (MACs).

Since the implementation of outpatient PPS, the AHA has advocated for the development of national guidelines and unique codes to represent facility resources, rather than physician resources, used in the delivery of clinic and ED visits. CMS has poor data to calculate crucial APC reimbursement since there is no standard definition or standard application of E/M codes. Since hospitals are using different methodologies, (time, interventions, patient complexity or severity, etc.), each hospital's reported E/M levels reflect a different aspect of hospital resource utilization.

In the 2007 outpatient PPS final rule, CMS indicated that "most commenters strongly supported creation of national guidelines." We are therefore puzzled as to why CMS continues to delay adoption of national guidelines. **The AHA continues to believe in the need for national guidelines for hospital ED and clinic visits.**

The reasons identified in previous comments from the AHA, as well as from other providers, regarding the need for national guidelines remain valid. In order to "play by the rules," a clear and detailed set of rules are needed. This becomes a more acute concern as CMS rolls out its

national Medicare Recovery Audit Contractors program. In the August 9, 2002 outpatient PPS proposed rule, a summary of the comments received by CMS regarding the need for national guidelines included the following reasons:

- Facilities need to comply with HIPAA requirements (concern that use of E/M codes with different reporting rules and meanings when used by facilities would violate HIPAA requirements for using the standard code sets);
- To set up effective audit and compliance programs;
- To minimize confusion on the part of coders;
- To minimize inaccurate payments; and
- To prevent gaming of the system.

In addition, given that CMS continues to delay approving or developing national guidelines, we recommend that CMS provide further clarification as to what services should be included or bundled in the E/M levels reported by hospitals. Hospitals continue to be confused by the use of CPT E/M codes to report hospital services for ED and clinic visits as evidenced by the multiple questions posed to CMS during Hospital Open Door Forums and to the AHA Central Office on HCPCS regarding the application of language in the introductory section of the Critical Care CPT guidelines. Hospitals have been confused by CMS' interpretation that CPT language regarding **physician** evaluation and management of ancillary services included in the Critical Care E/M also applies to hospital E/M coding.

Finally, the AHA recommends that once national guidelines are developed, a formal proposal should be presented to the AMA CPT Editorial Panel to create CPT codes for hospital visits. These codes then could be widely reported by hospitals to all payers.

OUTLIER RECONCILIATION

CMS proposes a number of changes to its outlier payment policy in an attempt to address concerns that some providers have improperly manipulated their charges in order to receive excessive outlier payments. Among these are proposals that would clarify when a Medicare contractor may substitute the statewide average CCR for a provider's CCR; allowing the provider to request or a contractor to use a different CCR under certain circumstances; and an outlier reconciliation process.

With regard to outlier reconciliation, CMS proposes allowing Medicare contractors to subject certain outlier payments to reconciliation when a provider's cost report is settled. CMS states that this would further ensure accurate outlier payments for facilities with CCRs that fluctuate significantly relative to the CCRs of other facilities. CMS does not define the reconciliation thresholds that would be applied, but notes that they would include a measure of acceptable percentage change in a provider's CCR and the outlier payment amounts involved. These thresholds would be set annually by CMS. The final outlier payments determined during

reconciliation would be adjusted for the time value of money. CMS proposes applying this reconciliation process to services provided on or after January 1.

The AHA supports approaches to ensure accurate outlier payments. Such a policy is already in place under the inpatient PPS, and its application to the outpatient PPS outlier policy makes sense. **However, we recommend that the effective date for this policy be the first cost reporting period in 2009, rather than January 1.** This should minimize administrative burden and prevent the confusion that could occur if it were to be initiated in the middle of a hospital's cost-reporting period.

In addition, our support for this policy hinges on the development of reasonable reconciliation thresholds. **We request that, in the final rule, CMS provide additional detail regarding how these thresholds will be calculated and at what level they will be set in 2009.**

Finally, we recommend a minor change to the regulatory language in order to ensure that CMS' new authority is used only for the purposes described in the preamble to the regulation. That is, we believe that the regulatory language proposed at the new 42 CFR 489.43(d)(5)(i) is too broad, seemingly placing no limits on the circumstances under which CMS may specify an alternative CCR. To make it clear that this new CMS discretionary authority to specify an alternative CCR is to be applied only under the circumstances described in the proposed regulation at 489.43(d)(5), **we recommend that 489.43(d)(5)(i) be changed as follows:**

*“(i) A hospital may request that its Medicare contractor use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS. CMS may also specify an alternative to the overall ancillary cost-to-charge ratio otherwise applicable under paragraph (d)(5)(ii) of this section **under the circumstances described in (d)(5)(iii) and (d)(5)(iv) of this section.**—A hospital may also request that its Medicare contractor use a different (higher or lower) cost to charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS.—”*

Partial Hospitalization Insights And Implications

American Hospital Association
and
National Association of
Psychiatric Health Systems

Background

- Declining median costs for partial hospitalization have raised questions and concerns for CMS, providers and their associations
 - CMS expanded its analysis in the 2008 and 2009 Proposed Rule by focusing on the number of services per day
 - AHA and NAPHS have deconstructed partial hospitalization in an effort to unravel the issues and provide insights for policy decisions

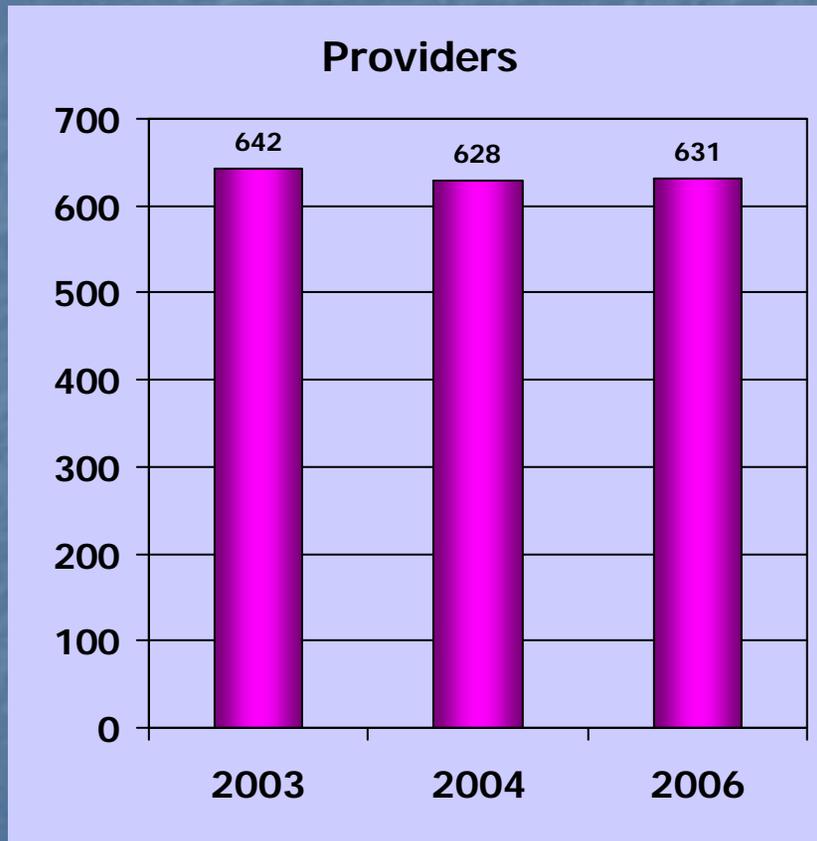
Partial Hospitalization Is Dominated By Only A Few Services

	2003	2004	2006
90853 Group psychotherapy	2,083,666	2,363,576	3,292,412
G0177 Training and education services	405,663	532,292	900,109
90857 Interactive group psychotherapy	292,964	372,088	538,926
G0176 Activity therapy	279,163	295,737	367,608
90816 Individual psychotherapy 20-30 min	31,309	29,785	31,271
G0129 Occupational therapy	29,965	32,164	23,259
90818 Individual psychotherapy 40-50 min	26,849	25,727	23,913
90801 Psychiatric diagnostic examination	9,929	10,647	11,700

Number of services reported, excluding quantities of 10 or more

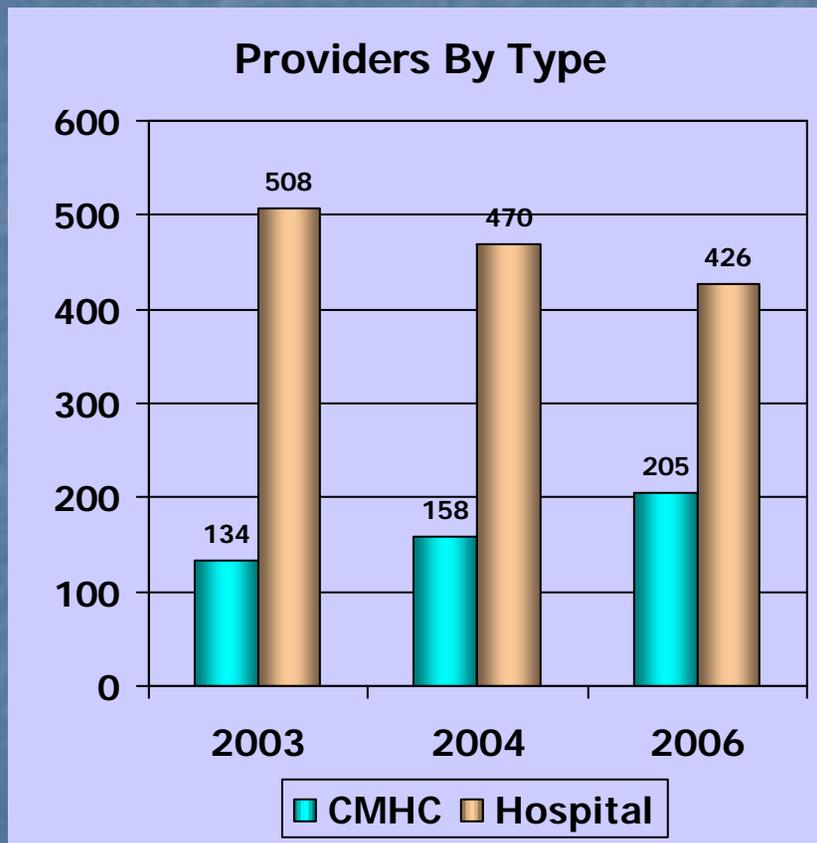
Regionalization

On The Surface, Providers Remained Relatively Stable ...



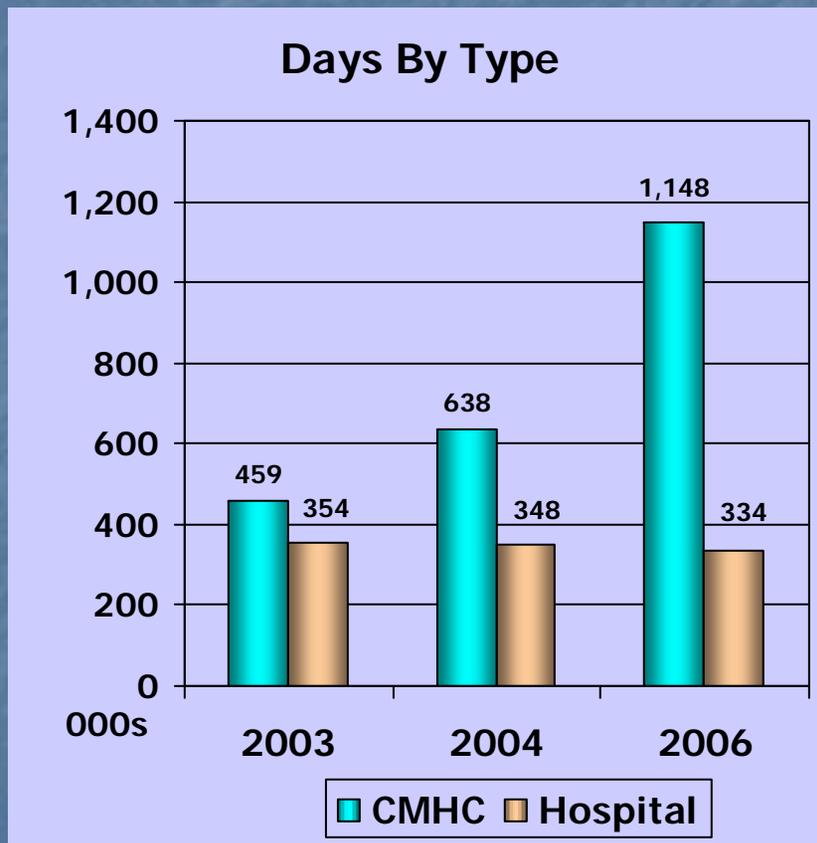
- The number of providers declined by less than 2%

... But The Mix Is Shifting Significantly



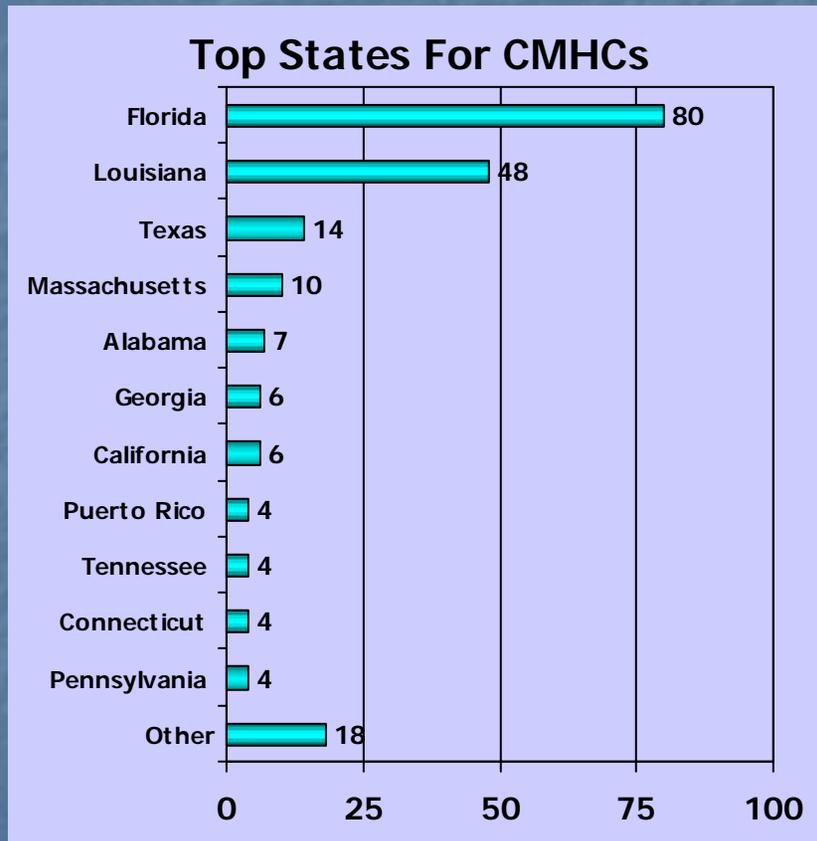
- Hospital providers declined by 16%
- CMHC providers increased by 53%
 - Florida, Louisiana and Texas accounted for almost all of the additional CMHCs

... And CMHCs Now Account For A Disproportionate Share Of The Days



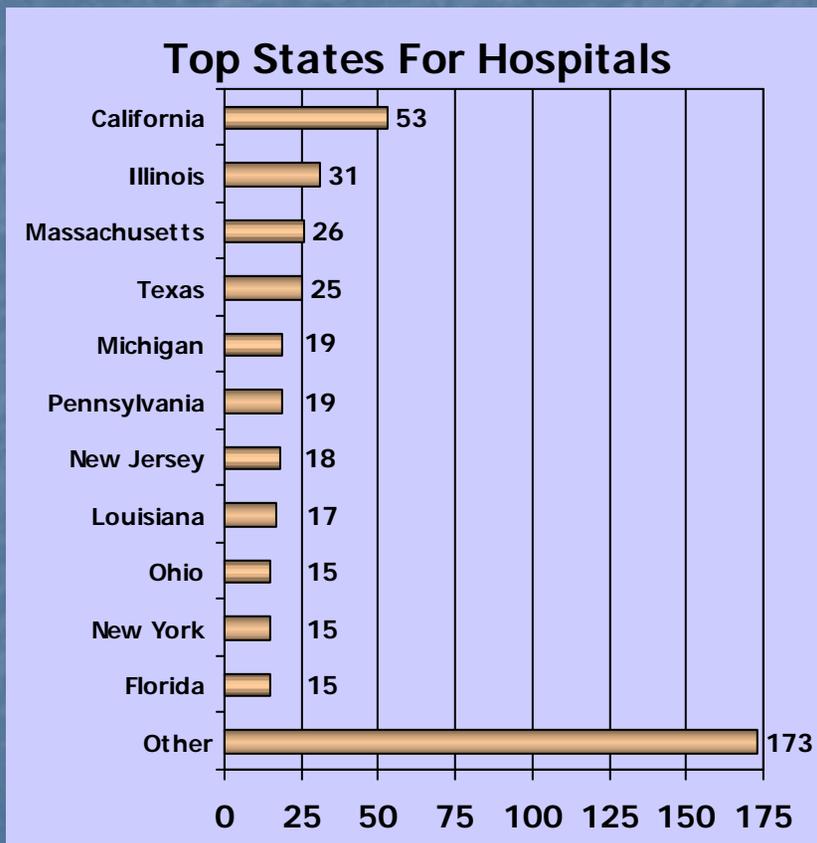
- CMHC days increased by 150%
- Hospital days decreased by almost 6%

CMHCs Are Concentrated In Southern States ...



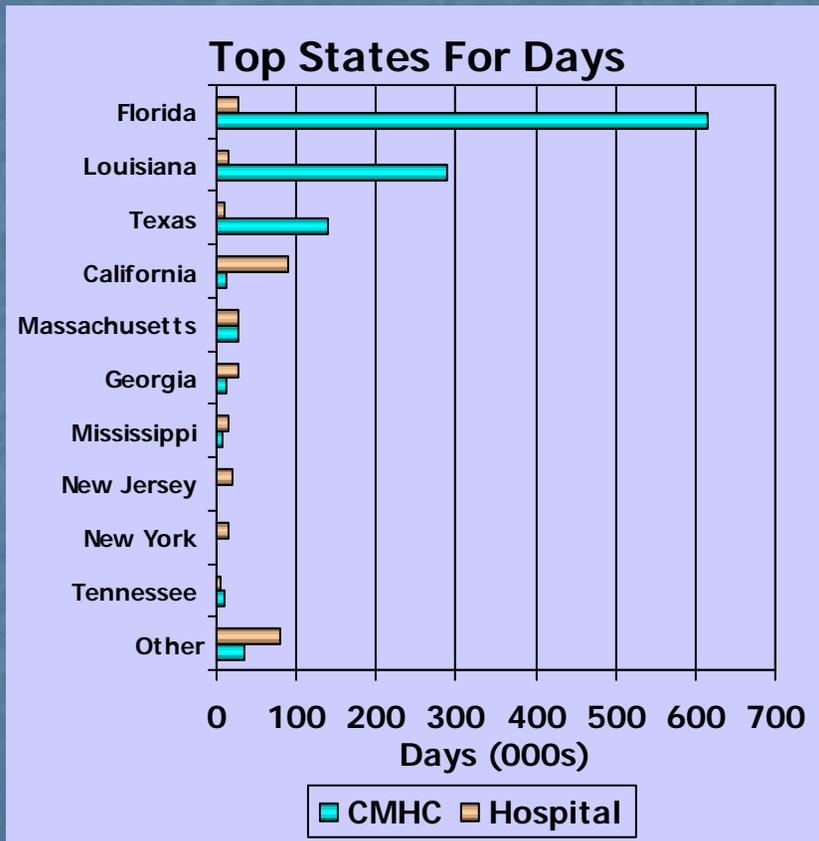
- In 2006, six southern states (FL, LA, TX, AL, GA, and TN) accounted for 78% of CMHC providers

... While Hospitals Are More Dispersed ...



- In 2006, the top six states accounted for only 41% of hospital providers
- Eleven southern states represent only 29% of hospital providers

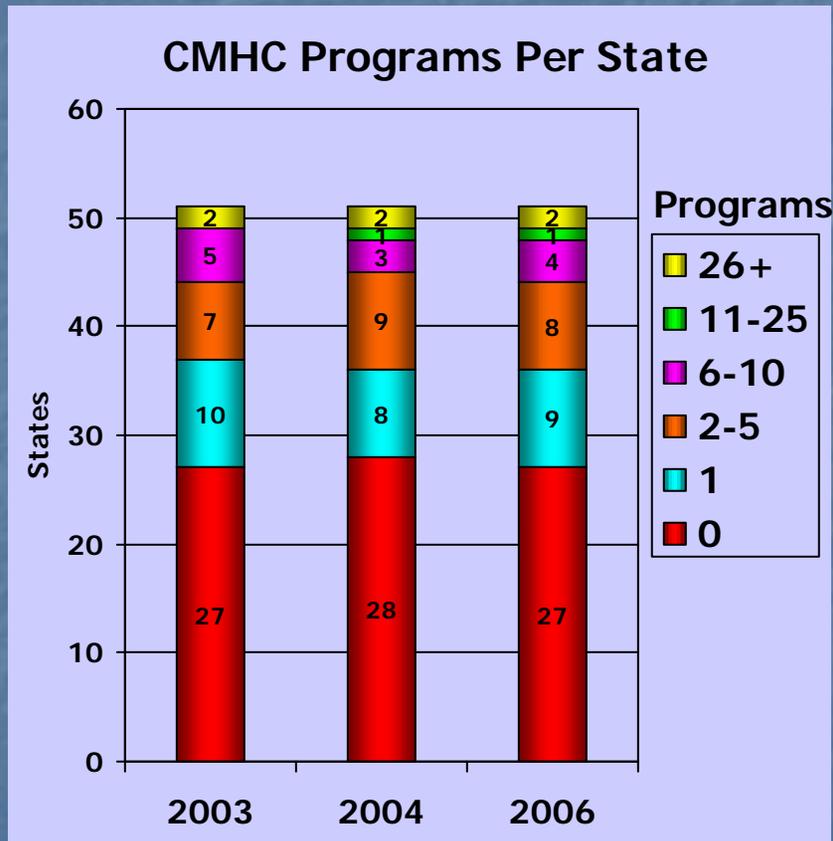
... But Just A Few States Account For The Vast Majority Of The Days



- Florida, Louisiana and Texas account for 74% of all days nationally

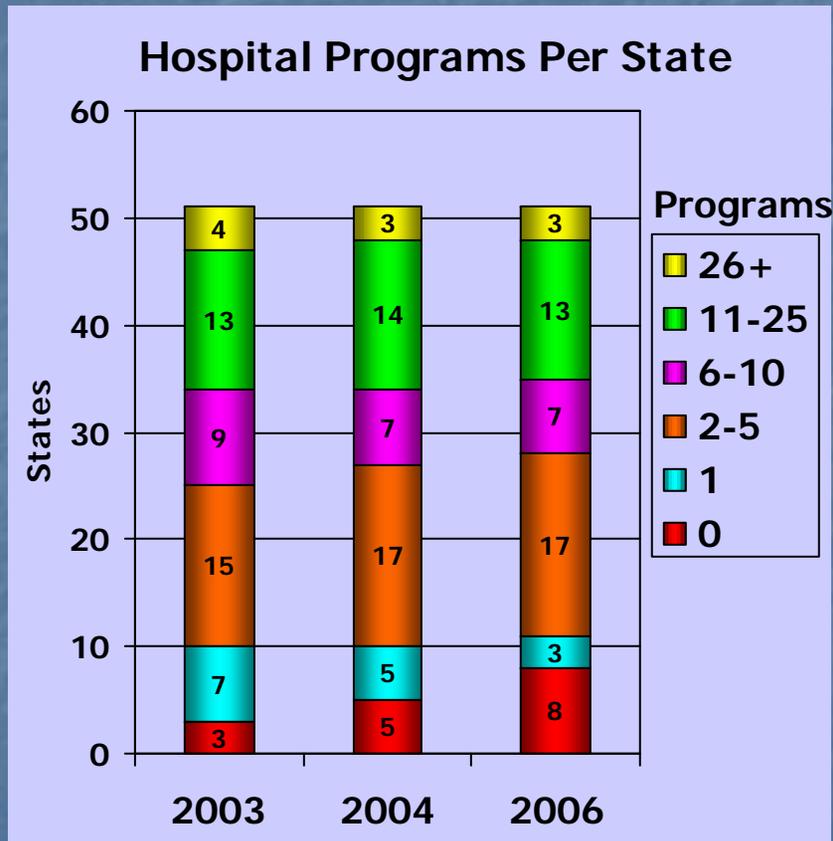
Access

CMHCs Are Unevenly Distributed Geographically ...



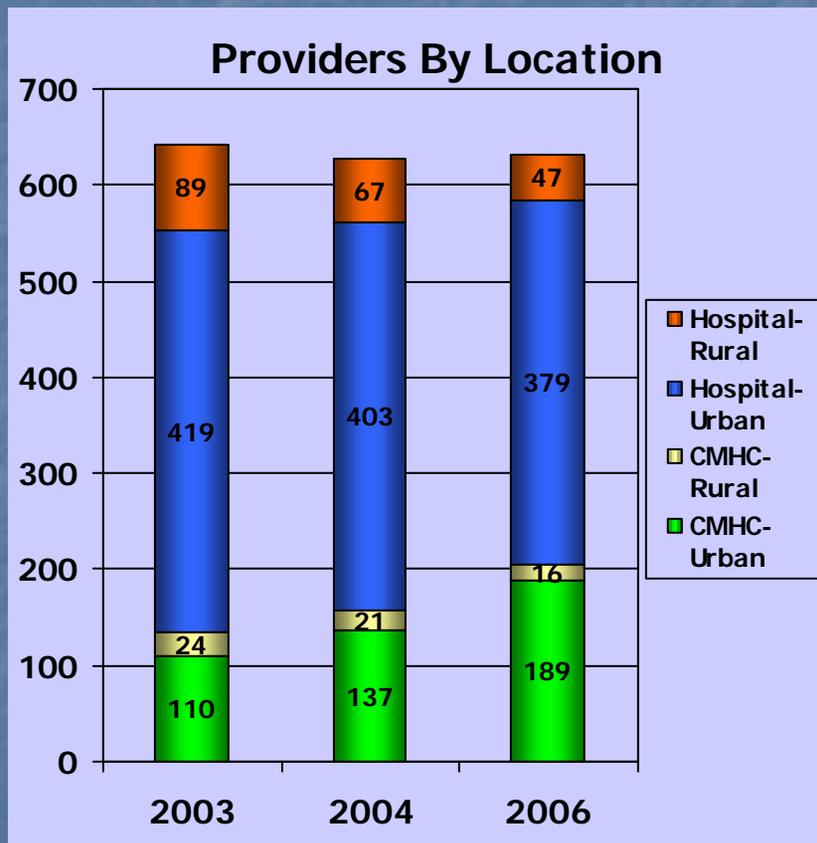
- More than half of states do not have a CMHC
- Only 30% of states have more than one CMHC

... While Hospitals Are More Widely Dispersed



- 80% of states have more than one hospital program
- However, the number of states without a hospital program is growing

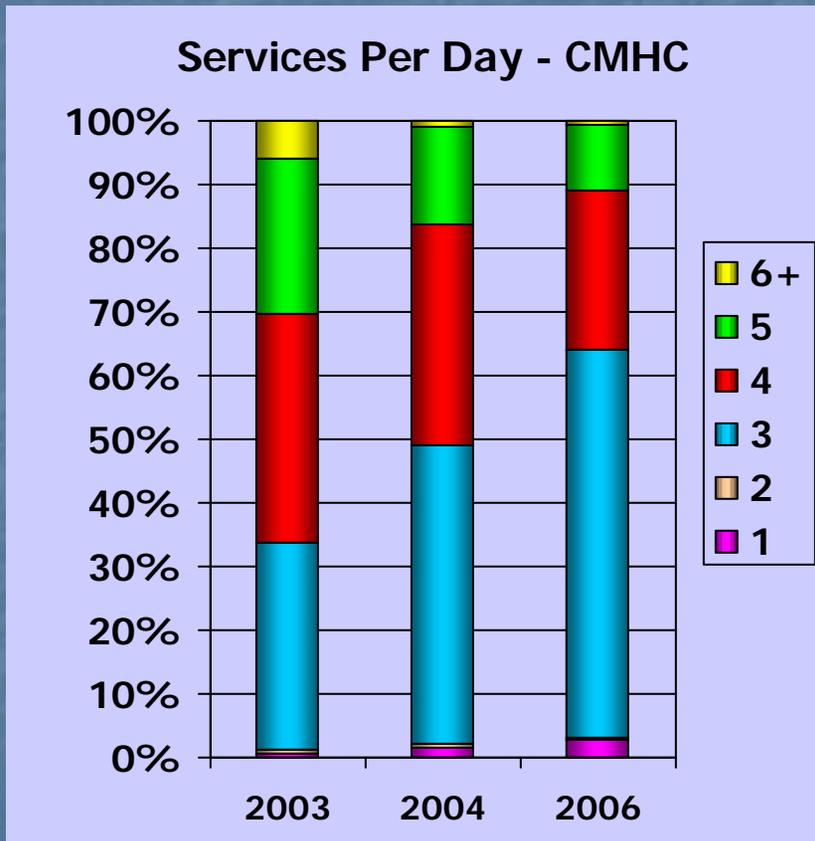
Rural Areas Experienced Significant Reductions In Providers



- Locations losing providers
 - 33% decline for rural CMHCs
 - 47% decline for rural hospitals
 - 10% decline for urban hospitals
- Urban CMHCs are the only group that is growing
 - 72% increase
 - However, Florida, Louisiana and Texas account for almost all of the growth

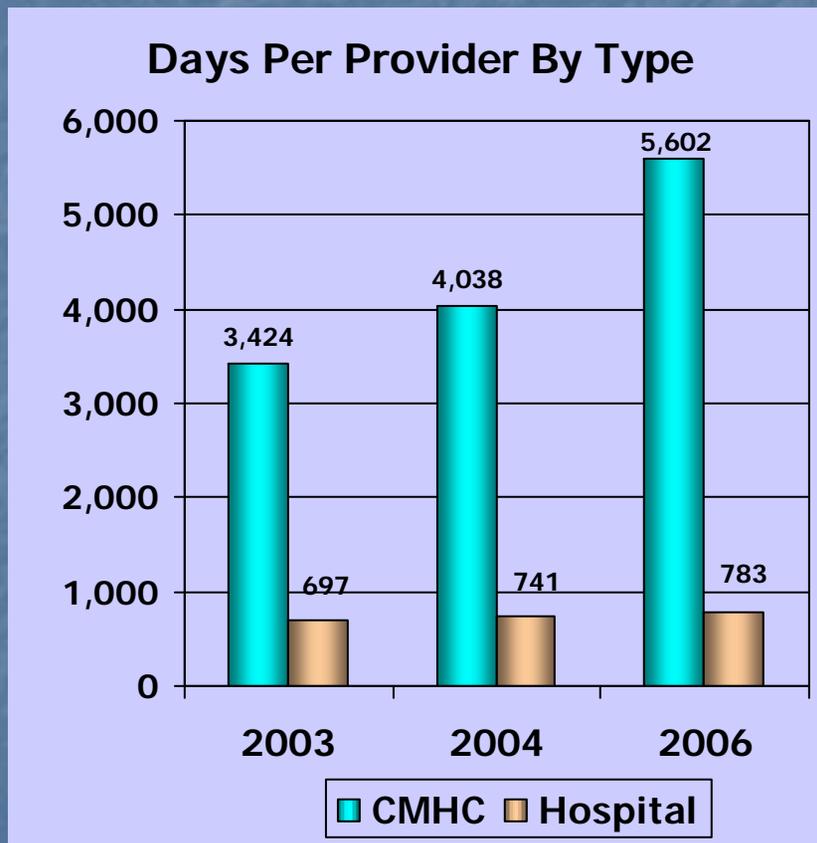
Divergent Strategies

CMHCs Responded To Lower Rates By Reducing Service Intensity ...



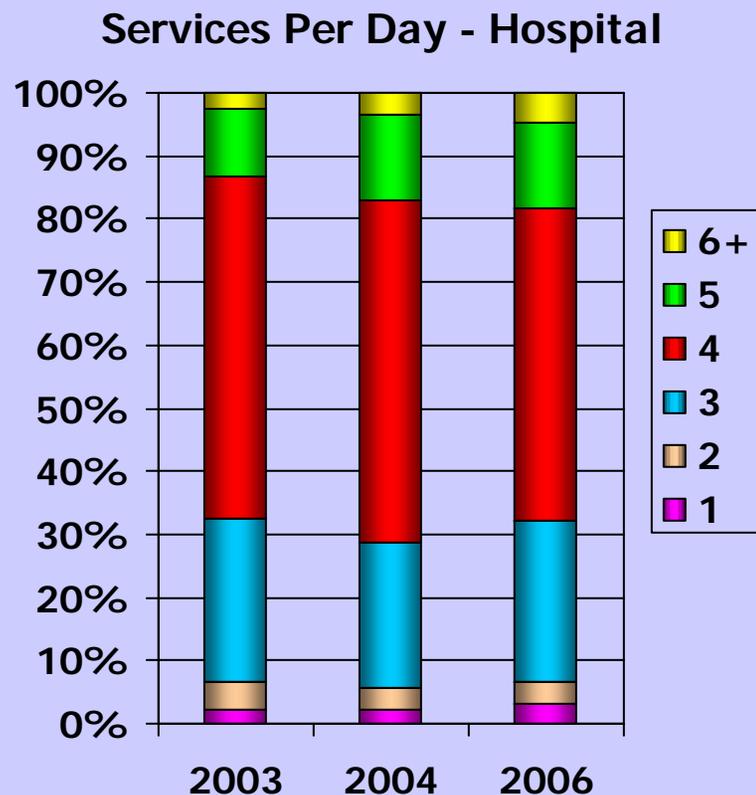
- CMHCs responded to the program's economic incentives
 - Days with 1-3 services doubled from one-third to two-thirds of CMHC days
 - Days with five or more services decreased from 30% to 11%
- In 2009 Proposed Rule, CMS shows this trend continues
 - Close to 75% of days have 3 or fewer services

... And Dramatically Increasing Volume ...



- Days per CMHC increased by 64%
- Days per hospital increased by 12%

... While Hospitals Maintained Their Service Intensity



- Hospitals remained committed to CMS' vision of partial hospitalization as a high intensity service despite decreased payment rates
 - Days with four or more services remained stable at just over two-thirds of hospital days
 - Days with five or more services increased from 13% to 18%

...and

- In the CY 2009 proposed rule, CMS shows this trend continues
 - Close to 75% of hospital PHP days consist of 4 or more services

Conclusions

- Partial hospitalization is becoming regionalized as CMHCs in a few states dominate and effectively set the rates for all providers
- As payment rates decline, access becomes an issue, particularly for rural areas
- Economic incentives have undermined the clinical intensity of the program

Proposals

- CMS' two-tier payment proposal is a good concept, but doesn't go far enough to promote service intensity and access
- CMS should use only hospital data to set PHP rates

Why Hospital Data Needs To Be Used To Set PHP Rates

PHP Rate Cap for OP Mental Health Services Only Affects Hospital Outpatient Services

- CMHCs are not eligible providers for hospital outpatient services
- Yet CMHC data affects the rate cap for hospital outpatient services
- A combined PHP rate potentially reduces access to outpatient hospital services

CMHC PHP Data Is Unstable

- CMHC median costs have wildly fluctuated (from highs of more than \$1,000 per day to lows of \$140) while hospital-based PHP median cost has been consistent and stable from the start of OPPS
- CMHC outlier payments have also fluctuated greatly

Hospital-Based PHP Data Is Reliable

- Hospital data is based on detailed and audited cost reports
- Hospital-based PHP median costs have been consistent and stable from the start of OPPS (ranging from \$200 to \$225 per day)

CMS Acknowledgement of Hospital and CMHC Differences

- CMS stated that:
 - “Hospital-based PHPs had remained in the \$200-\$225 range, while median cost for CMHC PHPs has fluctuated significantly (from a high of \$1,037 to a low of \$143)”
 - “Although we prefer to use both CMHC and hospital data to establish the PHP APC, as stated in the proposed rule we continue to be concerned about the volatility of CMHC data.”
 - “We stated in the proposed rule that we would continue to analyze the CHMC data in developing payment rates, and cautioned that we may use only hospital data in the future if the data continues to be unstable.”

Source: 2006 OPPTS Final Rule with Comments

Hospital-Based PHP Data Is National in Scope

- 80% of the states have two or more hospital-based PHPs....
- ...while 78% of CMHCs are in 6 southern states

Hospital-Based PHPs Are Meeting The Intent Of PHP Statute And CMS Rules

- More than 70% of hospital-based PHP days have 4 or more units of service
- In fact, hospital-based PHPs have increased the proportion of days with 4 or more units of service over the past few years – continuing to meet the needs of patients, while rates have been declining
- CMHCs have reduced units of service so that more than 73% of the days have 3 or fewer units of service

Partial Hospitalization Payment Rates Are Declining Dramatically

2005	2006	2007	2008	2009 (Proposed)
\$281	\$245	\$233	\$203	\$140 (3 services)
				\$174 (4+ services)

Our Proposal

Current rate (CY 2008)	2009 Proposed Rule	AHA/NAPHS Proposal
\$203 (all days)	<i>Use CMHC+hospital data:</i> \$140 (for 3 services)	<i>Use only hospital data:</i> \$151 (for 3 services)*
	\$174 (for 4+ services)	\$205 (for 4+ services)*

* Rates from CMS analysis contained in 2009 OPSS Proposed Rule

Financial Impact

	2008 PHP Payments	2009 Proposed Rule PHP Payments		2009 AHA/NAPHS Proposal PHP Payments	
	Estimate	Estimate	% Change	Estimate	% Change
CMHCs	\$232.4	\$169.4	-27.1%	\$189.9	-18.3%
Hospitals	\$65.9	\$50.7	-23.1%	\$58.5	-11.2%
Total	\$298.2	\$220.1	-26.2%	\$248.4	-16.7%

Estimates in millions based on CY 2006 partial hospitalization days

2008 Rate: \$203

2009 Proposed Rule Rates: 3 services = \$140 4 or more services = \$174

AHA + NAPHS Proposal Rates: 3 services = \$151 4 or more services = \$205

Financial Impact

- The current PHP rate of \$203 per day is about the same as that of hospital-based PHP days of 4 or more units of service (\$205)
- Any further reduction in rates will clearly impact access to PHP services in most states
- Many states only have hospital-based PHPs. If these programs close, it is likely more patients will be hospitalized – costing Medicare more money.

OPPS Is A Hospital Outpatient System Based on Hospital Data

- The PHP rates should be based on hospital data, which is:
 - reliable,
 - predictable, and
 - national in scope.