

August 26, 2009

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

RE: CMS-1414-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Proposed Rule (Vol. 74, No. 137), July 20, 2009

Dear Ms. Frizzera:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) proposed rule for calendar year 2010.

In the attached document, we provide detailed comments on several proposals. Specifically, we have serious concerns about CMS' proposal for physician supervision of "incident to" outpatient therapeutic services, the requirements for outpatient quality data reporting, the payment rates for separately payable drugs, and the continuing failure of CMS to require ASC quality and cost reporting. In brief, we make the following recommendations:

- We suggest several changes to CMS' proposal on physician supervision of outpatient therapeutic and diagnostic services to make the policy a better fit with the way in which health care is provided across the spectrum of hospital types. We recommend CMS:
 - Permit non-physician practitioners (NPP) to provide direct supervision for cardiac and pulmonary rehabilitation services, and clinical social workers should be permitted to supervise outpatient psychiatric services.
 - Revise the proposed definition of "direct supervision" to mean that the physician or NPP must be present on the same campus or in a location in close proximity to the campus and able to respond in a timely manner, in accordance with the hospital's or critical access hospital's policies, procedures, guidelines and/or bylaws, so as to be able to furnish assistance and direction throughout the performance of the procedure.



- Develop a more thoughtful and clinically-based approach for assigning levels of physician supervision to “incident to” outpatient therapeutic services at the service line level which would lead to the identification of specific services that require only general supervision, rather than direct supervision.
- While we are pleased that CMS decided not to adopt any more outpatient quality reporting measures at this time, we continue to have concerns about the four imaging efficiency measures that were adopted for use beginning with 2010. The AHA urges CMS to retire these OPSS measures for 2011.
- We disagree with CMS’ proposal to publicly report outpatient quality data that has not been validated. Unvalidated data should never be publicly reported on *Hospital Compare*.
- 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’ proposed payment methodology is flawed, and should be abandoned. Instead, we recommend that CMS pay for the acquisition cost of 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 continue to recommend the development of national guidelines for the coding of hospital emergency department and clinic visits. However, given CMS’ lack of progress in doing so, the AHA will reconvene its Coding Expert Panel to update its 2003 recommendations and submit these revised recommendations to the American Medical Association’s Current Procedural Terminology (CPT) Editorial Panel to create new CPT codes for hospital visits.
- We urge CMS to regularly report (via annual OPSS rulemaking) on outlier reconciliation activity, including the aggregate amounts recovered by provider type and region.
- In the interests of transparency and equity, we continue to urge CMS to implement a quality reporting system for ASCs as soon as possible. Finally, in order to allow for future validation of the appropriateness of ASC payment weights and rates, we recommend that CMS require ASCs to begin to routinely report cost data.

Thank you again for the opportunity to comment. Our detailed comments are attached. If you have any questions, please 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

American Hospital Association
Detailed Comments on the Outpatient Prospective Payment (OPPS) and
Ambulatory Surgical Center (ASC) Proposed Rule for CY 2010

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PHYSICIAN SUPERVISION

Proposed Policies for Direct Supervision of “Incident to” Outpatient Therapeutic Services

The Centers for Medicare & Medicaid Services (CMS) proposes policy changes for 2010 that would provide additional flexibility for the supervision of outpatient therapeutic services for hospitals and critical access hospitals (CAH). However, the AHA is disappointed that the 2010 proposed rule does not resolve the continued vulnerability for hospitals of unwarranted potential enforcement actions created by CMS’ characterization in the 2009 OPSS rule that a change in the physician supervision policy was merely a “restatement and clarification” of existing policy dating back to 2001. We strongly disagree with CMS’ characterization and urge the agency to rescind immediately its policy change, as discussed in our April 15 and June 1 letters (which are attached hereto and incorporated by reference herein) and other communications to CMS.

For the purposes of Medicare policy for 2010, the agency proposes to revise its policies for physician supervision to allow certain non-physician practitioners (NPP) to directly supervise hospital outpatient therapeutic services. In addition, for outpatient therapeutic services furnished in the hospital or in an on-campus provider-based department (PBD) of the hospital, CMS revises the definition of “direct supervision” to no longer require the supervising professional to be physically present in the same department where services are furnished. Instead the supervising professional must be present in the hospital or in an on-campus PBD and immediately available to assist.

CMS’ proposal is a step in the right direction; however, we recommend several changes – to the policy proposed for NPPs providing direct supervision, in the definitions of “direct supervision” and “in the hospital” and with regard to CMS’s discussion of the meaning of “immediately available” – to make the policy a better fit with the way health care is delivered across the spectrum of hospital types. Equally important, our recommendations would help preserve access to outpatient therapeutic services for Medicare beneficiaries, particularly in rural communities. Furthermore, we urge CMS to use its discretionary authority to develop a new framework for physician supervision that takes clinical factors into consideration in a more explicit way.

Non-Physician Practitioners May Provide Direct Supervision. Starting in 2010, CMS proposes that certain NPPs, specifically physician assistants (PA), nurse practitioners (NP), certified nurse specialists (CNS) and certified nurse-midwives (CNM), may directly supervise hospital outpatient therapeutic services that they are able to personally perform within their State’s scope of practice laws and hospital-granted privileges. CMS notes that due to statutory requirements, the direct supervision of cardiac rehabilitation, intensive cardiac rehabilitation and pulmonary rehabilitation must be furnished by a physician.

The AHA supports the proposal to extend direct supervision to NPPs. This flexibility will greatly help hospitals meet the new requirements for “direct supervision,” particularly in communities experiencing physician shortages. However, as our small, rural and critical

access hospitals have reminded us, it is not only physicians who are in short supply in their communities, it is also these NPPs. Rural hospitals, frontier hospitals and CAHs work hard to attract physicians and limited license professionals such as PAs, NPs, CNSs and CNMs to provide services in their communities. Many communities may have only one physician or NPP available in their locations, and some remote areas are only able to arrange for a physician or NPP to travel intermittently into the community to provide services at the hospital. A community that is successful in recruiting a nurse practitioner or other NPP would most likely not be bringing them into the hospital to supervise services only. Rather, they would be put into service as direct patient care providers furnishing services in their own practices which may or may not be located on the hospital campus and which may or may not be PBDs of the hospital. As we describe below, the AHA strongly urges CMS to acknowledge that these practical realities exist in small rural hospitals and CAHs and accept our recommendations regarding CMS' proposal to change to the definition of "direct supervision" and to newly define "in the hospital."

The AHA urges CMS to reconsider its decision to limit supervision of cardiac rehabilitation (CR), pulmonary rehabilitation (PR) and intensive cardiac rehabilitation (ICR) services to physicians only. The AHA disagrees with CMS' interpretation that Section 144 of the *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA), related to Payment and Coverage Improvements for Patients with Chronic Obstructive Pulmonary Disease and Other Conditions rules out supervision provided by NPPs. While MIPPA defines these as "physician supervised" services, it goes on to require that "a physician [be] immediately available and accessible for medical consultation and medical emergencies at all times items and services are being furnished under the program, *except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed.*" [Emphasis added]. The inclusion of this presumption makes it clear that Congress intended the leeway that was in place prior to 2009 for other outpatient therapeutic services furnished in the hospital and in on-campus PBDs to also apply to CR/PR/ICR services. As stated in the April 4, 2000 OPSS final rule, this meant that direct supervision "does not apply to services furnished in a department of a hospital that is located on the campus of that hospital." Instead, for these services, "we assume the direct supervision requirement to be met..."

While the 2009 OPSS final rule eliminated this assumption, it is logical to conclude that had Congress known that CMS would shortly be revising these regulations once again in order to provide additional latitude for other outpatient therapeutic services, it also would have supported extending these changes to CR/PR/ICR services. In fact, CMS seems to already recognize this intention on the part of Congress, as the agency also proposes in this rule to extend the new definition of "direct supervision" to CR/PR/ICR services. **Given this congressional intent to make equivalent allowances for CR/PR/ICR services furnished in hospitals, it is reasonable to apply CMS' additional flexibility permitting NPPs to provide direct supervision.** All the same reasons CMS proposes to allow NPPs to supervise other outpatient therapeutic services apply here as well. That is, CMS states that NPPs are recognized in statute and regulations as providing services that are analogous to physicians' services; Medicare Part B covers the professional services of these NPPs when the services would be covered as physicians' services

if furnished by a physician; and Medicare also makes payment for services provided “incident to” the services of these NPPs.

With regard to outpatient psychiatric services, such as partial hospitalization program (PHP) services provided in hospital outpatient departments, we recommend that CMS consider adding another discipline to the list of NPPs permitted to provide supervision. **We recommend that clinical social workers be permitted to supervise outpatient psychiatric services.** Under current regulations, clinical social worker services are covered by Part B as services that would be covered if furnished by a physician. The regulations at 42 CFR §410.73 (Clinical social worker services) state:

“(b) *Covered clinical social worker services.* Medicare Part B covers clinical social worker services.

(1) *Definition.* ‘Clinical social worker services’ means, except as specified in paragraph (b)(2) of this section, the services of a clinical social worker furnished for the diagnosis and treatment of mental illness that the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which the services are performed. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.”

For the psychiatric outpatient, clinical social workers are highly trained and qualified professionals who are equipped to perform comprehensive psychosocial assessment and are therefore familiar with all domains, the patient’s clinical, familial, social and support circumstances. They participate actively in the development and delivery of an individualized plan of active treatment, and typically provide the majority of psychotherapy to the patient. These professionals are best prepared to detect escalation early on and to intervene, averting crisis. It therefore makes sense that clinical social workers would be appropriate to provide supervision for outpatient psychiatric services, such as PHP services, including collaboration with the off-site physicians who order these services.

Refinements to the Definitions of “Direct Supervision,” “In the Hospital” and “Immediately Available.” Starting in 2010, CMS proposes to revise the definition of “direct supervision” of hospital outpatient therapeutic services for those services furnished in a hospital or in on-campus PBDs of a hospital. For services furnished on a hospital’s main campus, direct supervision means that the supervisory physician or NPP must be present on the same campus, in the hospital or in the on-campus PBD of the hospital, and immediately available to furnish assistance and direction throughout the performance of the procedure.

CMS also proposes to define “in the hospital” to mean areas in the main building(s) of a hospital that are under the ownership, financial and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital’s provider number. Therefore, the supervising professional may not be located in any other entity, such as a physician’s office or any other non-hospital space that may be co-located on the hospital’s campus.

Further, while CMS does not define “immediate” for direct supervision in terms of time or distance, it notes that the general definition of the word means “without interval of time.” Therefore, according to CMS, supervising professionals would not be considered to be immediately available if they were performing another procedure or service that could not be interrupted or so physically far away on the main campus from the location where the services are being provided that they could not intervene right away.

CMS states that its definition of “direct supervision” would continue to specify that supervising professionals must be available to furnish assistance and direction throughout the performance of the procedure. CMS explains that while this does not mean that they must be of the same specialty as the service or procedure being performed, the supervising professionals must have within their State’s scope of practice and hospital-granted privileges the ability to perform the service or procedure.

The AHA appreciates CMS’ efforts to provide additional flexibility to hospitals and CAHs regarding where the supervising professional is permitted to be when services are furnished on the hospital’s campus. However, these changes will not provide substantial relief for hospitals hoping to be able to continue providing on-campus outpatient therapeutic services in their communities. This is because the policy is severely hampered by the conditions and limitations CMS imposes. The way in which hospitals and CAHs provide supervision of outpatient services varies tremendously and the fact that these supervision arrangements may not technically meet the limitations of CMS’ proposed rule does not in any way diminish the fact that these services are currently provided in a high quality and safe way.

Our first concern is that the definition of “in the hospital” is overly restrictive and arbitrary. CMS proposes to define “in the hospital” to mean areas in the main building(s) of a hospital that are under the ownership, financial and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital’s provider number. As CMS notes in the preamble, the practical effect of this definition is to prohibit the supervising professional from being at any location that does not meet this definition, including a physician’s office, independent diagnostic testing facility, a co-located hospital, or hospital-operated provider or supplier, such as a skilled nursing facility, end-stage renal disease facility, or home health agency, or any other non-hospital space that may be co-located on the hospital’s campus.

This restriction in the physical location of the supervising professional is proposed without explanation and would prohibit many arrangements currently in place in hospitals that work well and ensure continued access to high quality outpatient services. For instance, in an academic medical center, this means that the supervising professional may not be in any on-campus area of the center that has been leased to the faculty, such as faculty academic offices, even if these academic offices are located in close proximity to the PBD where outpatient therapeutic services are being furnished. In rural and other areas, the hospital or CAH may lease space on its campus to physicians for their private practices. These offices may be across the hall from the hospital

service, however due to the restrictive definition of “in the hospital,” this arrangement would be prohibited. Further, some hospitals lease space within their facilities to other interests such as restaurants, parking facilities, or other kinds of retail establishments. The proposed definition of “in the hospital” would prohibit supervising professionals from entering into any such area, for instance to purchase a meal, during hours that services are being provided.

A policy that would result in hospitals or CAHs having to hire and pay physicians and/or NPPs to do nothing other than supervise would have significant implications, both in terms of costs and patient access to care. In rural areas, doing so may be impossible given the shortage of physicians and NPPs. Even if there are professionals in the community, it is unlikely that they would be willing to leave or otherwise limit their private practices in order to supervise. Moreover, paying for supervision services would be a barrier for many vulnerable rural hospitals and CAHs. If compliance is impossible due to personnel shortages or high costs, hospitals may be forced to shut down services or severely restrict their hours of operation. The impact on patient access to care, particularly in rural areas would be severe. Patients seeking chemotherapy infusion or blood transfusions would be forced to travel long distances to obtain their life-saving treatments. The same implications exist for hospitals that provide outpatient psychiatric services – given the shortage of psychiatric professionals and the decline in payments for PHP services over time, hospitals may choose to discontinue these services, rather than attempt to comply with CMS’ proposed regulations. In fact, the numbers of hospital-based PHP programs has been declining even in the absence of this additional costly new requirement.

We do not understand why it matters that the supervising professional be constrained to only areas on the hospital’s campus that are under the hospital’s control. In fact, a supervising professional may actually be more accessible and physically closer to patients receiving “incident to” services in such a “non-hospital” location than if he or she is in an area that would currently comply with the proposed definition, such as in a different on-campus PBD. Instead we believe that the relevant issue is whether the supervising professional is available and able to respond in a timely way, while procedures or services are being furnished, to address any patient issues that may arise.

The AHA also is concerned about CMS’ preamble statement that the general definition of the word “immediate” is “without interval of time.” While CMS is not proposing to adopt this definition in regulation nor is it proposing to define “immediate availability” in terms of time or distance, the mere fact that CMS has made this statement essentially negates the flexibility that CMS purports to propose in this rule. If CMS really means that its expectation is that a supervising professional must be able to physically arrive at the patient’s bedside “without interval of time” then the standard being proposed is one of personal supervision and not direct supervision. According to 42 CFR 410.32 (b)(3)(iii), personal supervision means a physician must be in attendance in the room during the performance of the procedure.

The AHA does not believe that this is what CMS intended to do, and therefore **we strongly recommend that CMS establish a new definition for “direct supervision” that no longer uses the words “immediately available” and eliminates the problematic definition of “in the**

hospital.” Instead, CMS should consider what is really necessary to ensure that a supervising professional is able to respond in order to furnish assistance and direction throughout the performance of the procedure.

We recommend that CMS establish a new definition of direct supervision for “incident to” services furnished in on-campus PBDs of the hospital that emphasizes the supervisor’s ability to respond in a timely way, regardless of whether he or she is physically located in the hospital or an on-campus PBD of the hospital. This approach would share certain elements used for on-call specialists in the emergency department (ED); it would require hospitals or CAHs to develop, and ensure compliance with, policies, procedures, guidelines and/or bylaws that specify the availability and response expected from supervising professionals. In addition, supervising professionals should have an understanding of how the outpatient therapeutic services they supervise are being furnished in PBDs. As such, hospitals should involve supervising physicians and NPPs in the development of performance standards and measures for services they will be supervising.

The AHA recommends that CMS define “direct supervision” to mean that the physician or NPP must be present on the same campus or in a location in close proximity to the campus and able to respond in a timely manner, in accordance with the hospital’s or CAH’s policies, procedures, guidelines and/or bylaws, so as to be able to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or NPP must be present in the same room where the procedure is performed.

In addition, we believe that the term “available to respond in a timely manner” should not be limited to the physical presence of the supervisor at the patient’s bedside. With this Administration’s focus on advancing the applications of technology in health care, including telemedicine and robotic technologies for health care delivery, **we recommend that direct supervision should explicitly include, as appropriate, response via radio or telephone, or through other technologies, such as telemedicine, approved for use in Medicare.**

A New Approach is Needed for Physician Supervision of Outpatient Therapeutic Services. In addition to the improvements to CMS’ policy we recommend above, a more thoughtful approach to physician supervision should be put into place that takes clinical factors into consideration when determining how physician supervision should be provided. CMS has the discretionary authority to make such significant changes to its physician supervision policy. Medicare covers and pays for outpatient therapeutic hospital services as services furnished “incident to” a physician’s service, as described in *Social Security Act* §1861(s)(2)(B). The law does not mandate a specific level of physician supervision for “incident to” services. It is entirely within CMS’ regulatory discretion to determine the appropriate level of supervision for these services.

Currently, CMS’ broad brush approach to physician supervision of outpatient therapeutic services makes no distinctions in services based on their complexity or risk. For example, a simple injection of a pain medication requires the same level of physician supervision as a heart defect repair procedure. By contrast, the way in which supervision is provided for outpatient

diagnostic services takes a different approach in which individual outpatient diagnostic services are assigned to one of three levels of physician supervision – general, direct or personal – depending on the nature of the service.

A more thoughtful and clinically-based approach is needed for assigning levels of physician supervision to “incident to” outpatient therapeutic services at the service line level. **We recommend that CMS develop a process, informed by its medical staff and subject to public comment, which would lead to the identification of specific services that require only general supervision, rather than direct supervision.** Such an approach should define the clinical and other factors that ought to be considered when determining the level of supervision needed for a particular outpatient therapeutic service. According to 42 CFR 410.32 (b)(3)(i), general supervision means “the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure.” Examples of the types of services that we believe may require only general supervision are most outpatient psychiatric services (such as partial hospitalization), hydration services, simple injections and follow-up wound care.

Areas Requiring Clarification. The AHA requests that CMS provide clarification regarding the following issues.

- Which hospital outpatient services are included as “incident-to” services subject to provisions of this proposed rule? The relevant manual section, *Pub. 100-92, Medicare Benefit Policy Manual*, at *Section 20.5.1. Coverage of Outpatient Therapeutic Services Incident to a Physician’s Service Furnished on or After August 1, 2000* provides only a very general description, stating, “Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services.” **We recommend that CMS provide a more definitive list of services that are considered to be “incident to” outpatient therapeutic services, either by CPT/HCPCS codes and/or revenue code.**
- Does CMS intend to permit NPPs to provide supervision for those outpatient *diagnostic* services that require “direct supervision?” This is not clear from the proposed rule. If this is not CMS’ intention, we request that an explanation for this decision be provided in the final rule.
- Under CMS’ proposed policy, would a physician or NPP be permitted to be located within an on-campus provider-based rural health clinic if the outpatient therapeutic services he or she is supervising were being furnished in a PBD located elsewhere on the hospital’s or CAH’s campus?
- Given the provisions in this proposed rule, how would a hospital be able to bill a service that was initially provided on an inpatient basis as an outpatient service, for example in a condition code 44 situation? That is, because the service is initially provided as an inpatient service, the decision to bill it as an outpatient service may be difficult if direct supervision were not provided when the service was rendered.

- If a physician is directly furnishing an “incident-to” outpatient therapeutic services in a hospital or a PBD, is direct supervision still required?

Finally, with regard to outpatient diagnostic services, the AHA recommends that CMS include an additional column in Addendum B in the final rule that describes the required level of supervision for these services. This would make it easier for hospitals to determine their compliance with current requirements.

OUTPATIENT PPS: QUALITY DATA

Reporting of Hospital Quality Data

The Tax Relief and Health Care Act of 2006 mandated that CMS establish a program under which hospitals must report data on the quality of hospital outpatient care to receive their full annual update to the outpatient PPS payment rate. Beginning in 2009, hospitals that fail to report data incur a reduction in their annual payment update factor of 2.0 percentage points.

In general, we would like to comment on the process and criteria used by CMS to select quality measures for its reporting programs. The quality measures selected for public reporting purposes should be driven by a common set of national priorities for quality improvement and public reporting. The use of a common set of priorities would help focus providers’ quality improvement efforts on high-leverage, important areas, and it would help align the various national reporting programs among different health care providers and settings. These national priorities exist in the work of the National Quality Forum’s (NQF) National Priority Partners in which CMS and other federal agencies participate. The goal of the national priorities is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care. The Hospital Quality Alliance (HQA) has agreed that the National Priorities Partners national goals should provide a foundation for its future work. We urge CMS to follow these national goals as well when it selects future measures for the outpatient pay-for-reporting program.

The Tax Relief and Health Care Act of 2006 required the Secretary to ensure, to the extent feasible and practicable, that the outpatient quality measures be endorsed by one or more national consensus building entities. While CMS states in the proposed rule that it generally prefers to adopt measures that have been endorsed by the NQF, the agency states that it can determine a consensus among affected parties by other means as well. We believe the only national consensus building entities that meet the definition in the statute are the NQF and the HQA. Through the NQF, interested health care stakeholders come together to choose measures that are useful for quality improvement and public reporting. Through the HQA, public and private partners together identify areas to focus on that are critical to hospital patients and, from among the NQF-endorsed measures, select those that best assess quality in those priority areas. **It is necessary that any measures added to the pay-for-reporting program first go through the rigorous, consensus-based assessment processes of both the NQF and HQA.** Given the number of NQF-endorsed and HQA-adopted measures currently available for use, it is both feasible and practicable for CMS to choose only NQF-endorsed and HQA-adopted measures.

Quality Measures for 2011. We are pleased that CMS does not propose any new outpatient quality reporting measures at this time. **However, we continue to have concerns about the four imaging efficiency measures that were adopted for use beginning with 2010, and we urge CMS to retire these measures from the outpatient pay-for-reporting program for 2011.** As we stated above, all measures used for the outpatient pay-for-reporting program should be NQF-endorsed and HQA-adopted. Of the four imaging efficiency measures, none is HQA-adopted and only two have been endorsed by the NQF. The two non-NQF endorsed measures are not only inappropriate for the reporting program, but have the potential to cause patient harm. Our specific concerns with the measures are outlined below:

- *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 used 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, and thus, there is no accepted best practice. Without evidence that tells what the appropriate number of combined studies, those performed both with and without contrast, providers will be unable to evaluate their own performance against a best practice, and the public will find it difficult to interpret the results of the measure. Further, the measure contains a number of patient exclusions, and the applicable patient population is unclear.
- *Mammography Follow-up Rates.* This measure assesses the follow-up, or recall, rate of an imaging facility providing mammography services. This measure should not be used. 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, leading to a lack of information about best practices. This measure is currently not risk-adjusted, but because patient population characteristics vary among hospitals, it should be adjusted to reflect any baseline differences among the patients seeking services at different providers. We are concerned that inappropriate application of this measure could result in unintended consequences for patients. The measure implies that high follow-up rates are clinically undesirable. However, 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 16 additional measures for possible implementation in the outpatient reporting program for 2012 or later and requests comments on the appropriateness of these measures. We are unable to provide detailed comments without evaluating complete outpatient hospital technical specifications; however, below are our preliminary thoughts on some of the proposed measures.

Measure #2, Adjuvant Hormonal Therapy for Patients with Breast Cancer and Measure #3, Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection – Both measures show promise in assessing an important health condition, cancer, for which no national hospital quality measures currently exist. However, we have concerns with CMS' ability to

implement measures that are collected through data registries. One of the largest challenges with using registry data for national public reporting is the difficulty of validating any data collected by a third party. CMS proposes a validation method to check data that are collected by the hospitals and submitted directly to the agency. For data submitted to a registry, a different validation process would be needed, as the registry may or may not manipulate the data before transferring it to CMS for use in a national reporting program. The development of such a process to validate registry data is a critical step that must be completed before registry data should be reported on the *Hospital Compare* Web site.

An additional concern with CMS' use of registry data for public reporting programs is that many clinical registries require hospitals to pay a fee to participate, and these fees can be costly. By requiring hospitals to participate in clinical data registries that impose fees on providers, the Medicare program could be viewed as serving the financial interests of third-party organizations. This is an inappropriate position for the federal government to take, and we urge CMS to think carefully about how to avoid this situation.

Measure #4 – Median Time from ED Arrival to ED Departure for Discharged ED Patients – As structured, this measure includes the time spent while patients are actively receiving care, in addition to the time spent waiting in the ED. It is illogical to include the time spent receiving care in this measure. For patients discharged back into the community, and not admitted or transferred to another facility, there is no wait time in the ED after the patient has received all appropriate care. Thus, for these patients, any time spent waiting in the ED occurs before they see a provider. We suggest CMS modify the measure so that it reflects only the time spent waiting in the ED to see a provider.

Measure #12 – SPECT MPI and Stress Echocardiography for Preoperative Evaluation for Low-Risk Non-cardiac Surgery Risk Assessment – We are concerned that there is no known benchmark for the appropriate rate of SPECT MPI and stress echocardiography among the measure population. Without a benchmark, providers could not use the measure for quality improvement purposes, nor would it be relevant to patients for making decisions about their care, as it would be difficult to interpret each provider's rate.

The measure attempts to capture those SPECT MPIs and stress echocardiography tests that are delivered for the purposes of pre-operative evaluation. However, as the measure will be calculated from Medicare claims, it is unclear how information about the purpose of the test will be captured. To our knowledge, this information would be available only in a patient's medical record, and not from a patient's Medicare bill.

Measure #13 – Use of Stress Echocardiography or SPECT MPI Post-Revascularization Coronary Artery Bypass Graft (CABG) – There is no known benchmark for the appropriate rate of SPECT MPI and stress echocardiography among the measure population. This raises concern that the measure is neither useable to providers nor relevant to patients, as it will be difficult to interpret how well each provider is performing.

The measure's long time span of a five-year period post-CABG hinders its usability. It is hard to believe that, absent a fully interoperable national health information technology system, a facility where a patient seeks to receive a SPECT MPI or stress echocardiography will have information available on the patient's medical history for the past five years. Patients may move or change primary care physicians during the five-year follow-up period, making it very difficult to track their medical history. This seemingly inevitable lack of information will make it impossible for the imaging provider to determine whether or not the test is appropriate for a patient, and, therefore, it will be impossible for providers to take action to improve their performance on this measure. The five-year timeframe also raises concerns that the information will be unavailable for a number of years and be irrelevant by the time it is available.

Measure #14 – Use of Computed Tomography in ED for Headache – This measure targets an important area where overuse of diagnostic imaging tests may be present to the detriment of patient care. From the preliminary information released by the measure developer, the measure appears to be generally well-specified, feasible and useable to both providers and consumers. However, because the measure will be calculated only from Medicare claims, information on the services delivered to patients with other insurance coverage will not be available. This will provide an incomplete picture of the care delivered by imaging providers.

Measure #15 – Simultaneous Use of Brain Computed Tomography and Sinus Computed Tomography – Similar to the measure of the use of computed tomography in the ED for headache, this measure identifies a potentially important area of overuse of diagnostic imaging tests, and the preliminary specifications of the measure appear valid and useable for both providers and consumers. But, because this measure would be calculated from Medicare claims, it would present an incomplete picture of the care delivered to all patients treated in the emergency department.

Program Procedures. For the first time, CMS specifies many of the outpatient pay-for-reporting program's processes in detail. The AHA appreciates this specificity. It is helpful for hospitals to have clear direction on both the requirements and the process of the pay-for-reporting program. The AHA generally supports the program procedures as outlined in the proposed rule, including the proposal to no longer require hospitals to maintain current designation of a QualityNet administrator.

Extraordinary Circumstances Extensions and Waivers. The AHA appreciates CMS' recognition that hospitals facing certain extraordinary circumstances, such as a hurricane that damages or destroys the hospital, should be granted an extension or waiver of the outpatient pay-for-reporting program requirements. Although we believe decisions on granting an extension or waiver would be best made on a case-by-case basis depending on each hospital's unique situation, we suggest that CMS develop some general criteria of when such extensions or waivers would be granted. We also remind CMS that when a hospital is damaged or destroyed, the agency's usual means of communicating to the hospital, such as over the QualityNet Exchange or by mail, may be impossible. Thus, we are concerned that CMS' proposal to require hospitals to file a request form for an extraordinary circumstances waiver within 30 days of such

as event may not be feasible for hospitals in these situations. We urge the agency to develop a creative and flexible approach to working with hospitals in these situations to ensure that an undue burden is not placed on hospitals during a time of hardship.

Data Validation for 2011. For 2011, CMS proposes to implement a temporary validation program under which hospitals would be required to participate and submit medical records for validation review, but the results of the validation would not affect their payment determination. CMS would provide feedback to hospitals on their validation results so that hospitals may learn from the experience. The AHA applauds CMS proposal for data validation. Hospitals will benefit from this program as they continue to gain experience with outpatient quality reporting. CMS states that its sampling methodology could include up to 20 randomly selected patient cases per hospital. We suggest that CMS build safeguards into the sampling process to ensure that no more than 20 patient cases are selected for each hospital.

Data Validation for 2012 and beyond. CMS proposes a new process for validating hospitals' outpatient quality data beginning in 2012. Under the proposal, CMS would review 48 medical charts (12 per quarter) from 800 randomly selected hospitals each year. The review would assess the accuracy of each hospital's measure rate, reflecting whether or not the hospital classified patients appropriately into the measure denominators and numerators. **The AHA believes that the framework of CMS' proposed process holds promise as a reasonable approach to ensure the accuracy of the quality data and improve upon the deficiencies in the current inpatient program validation process.**

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.

To pass validation, CMS proposes that hospitals meet a minimum of 90 percent reliability from chart validation. We believe that this is far too stringent a requirement in the first year of data validation. The current inpatient quality reporting data validation program uses an 80 percent reliability threshold. The new inpatient validation program just finalized by CMS in the 2010 inpatient PPS final rule, which is very similar to the proposed outpatient program, would require a 75 percent reliability threshold. **CMS should set the reliability threshold for the outpatient program at 75 percent, the same as in the inpatient PPS.**

Targeted Approach to Data Validation. 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.

Publication of Outpatient Quality Data. We disagree with CMS' proposal to publicly report outpatient quality data that has not been validated. In the 2009 outpatient PPS final rule, CMS stated that it would not publicly report quality data that had not been validated. However, in the 2010 proposed rule, CMS changes its position and proposes to report outpatient quality data beginning with data from third quarter 2008, regardless of whether those data have been validated for payment determination purposes. While we would like to see the outpatient quality data reported as soon as possible, unvalidated data should never be publicly reported on *Hospital Compare*. Data for the inpatient reporting program were validated before they were publicly posted, and the outpatient data should be as well.

HEALTHCARE-ASSOCIATED CONDITIONS

CMS does not propose to expand its healthcare-associated conditions policy to the hospital outpatient setting at this time. Rather, the agency continues to gather feedback on this topic and evaluate the impact of the inpatient healthcare-associated conditions policy. We support CMS' evaluation of the inpatient policy and believe that a robust program evaluation should be conducted before CMS considers expanding the healthcare-associated conditions policy to other settings.

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 2010, the law requires that payment for these specified covered outpatient drugs (SCOD) be equal to the average acquisition cost for the drug, subject to adjustment for pharmacy overhead costs (the significant costs of safely preparing drugs for administration). Consistent with its current policy, CMS proposes to apply the SCOD payment methodology to all separately payable drugs.

For 2010, CMS proposes to pay for the drug acquisition *and* pharmacy overhead costs of separately payable drugs and biologics at a *combined* rate of average sales price (ASP) plus 4 percent. This is the same amount paid in 2009. However, CMS calculates the 2010 rate using a revised methodology. The revision attempts to address stakeholders' concerns about the negative impact that charge compression and the drug packaging threshold have on the payment rates for separately payable drugs using CMS' standard methodology.

First, the agency applies its standard drug payment methodology, using hospital claims data and cost reports to estimate the cost of separately payable drugs, arriving at a payment rate of ASP *minus* 2 percent. Then, CMS proposes to make a payment adjustment that redistributes pharmacy overhead costs, in the amount of \$150 million, from packaged drugs to separately

payable drugs. This boosts the proposed payment rate for separately payable drugs to ASP plus 4 percent. In order to make this redistribution budget neutral within drugs and biologicals, and not reduce payments for other services, CMS proposes to reduce payments for packaged drugs by about 27 percent.

CMS notes that the amount of overhead cost redistribution that would be appropriate in a payment system that is fundamentally based on averages is not fully evident, but settles on \$150 million as a “middle ground.” In explaining its decision to redistribute a portion of the pharmacy overhead from packaged to separately payable drugs, the agency assumes that between one-third and one-half of the \$395 million in pharmacy overhead costs that CMS estimates is currently associated with packaged drugs and biologicals is misapplied, as a function of charge compression and the agency’s choice of an annual drug packaging threshold. Based on these analyses, CMS claims its proposal offers a more appropriate allocation of pharmacy overhead cost to separately payable drugs and biologicals.

CMS further proposes to include claims data for 340B hospitals in the calculation of payment for drugs and biologicals under the 2010 OPSS and that 340B hospitals would be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program.

The AHA appreciates CMS’ recognition of flaws in its current rate-setting methodology. We also agree that it is important to pay for separately payable drugs in a manner that is administratively simple. **However, the AHA believes that the reallocation of \$150 million and the resulting payment rate of ASP plus 4 percent is inadequate.**

The AHA continues to recommend that CMS pay for separately payable outpatient drugs at least at the rate at which they are paid in physician offices – ASP plus 6 percent. Paying for separately payable drugs under the OPSS at ASP plus 4 percent, while maintaining drug payments at ASP plus 6 percent for drugs provided in physician offices, creates payment inconsistencies that could lead to 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.

The Social Security Act, at Section 1833(t)(14)(A), requires CMS to 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 Government Accountability 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 (CAP). 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.

A growing body of evidence shows that CMS' methodology for calculating payment for separately paid drugs is contrary to statute and fails to adequately address problems in the claims data. Neither the GAO nor CMS has conducted surveys of hospital acquisition costs since 2004. Further, the methodology CMS proposes to use is not a survey but rather is based on an inaccurate extrapolation from claims data and an unsustainable redistribution of an arbitrary amount of the pharmacy overhead cost from packaged drugs to separately payable drugs. CMS' methodology also is unstable – that is, the resulting ASP plus X percent payment amount is extremely sensitive to even relatively minor changes in calculations, assumptions, or overhead allocation methodologies.

Although CMS states that its methodology represents the “middle ground” resulting in “a more appropriate allocation of drug and biological cost to separately payable drugs and biologicals,” several analyses show that CMS' methodology produces rates that do not represent hospital acquisition costs and pharmacy overhead costs. For instance, based on a 2004 survey, the GAO reported that actual drug acquisition costs of hospitals, *not including overhead*, were ASP plus 3 percent. Most recently, CMS' own contractor, RTI International, found that CMS' methodology substantially underestimates the costs of acquiring and supplying separately paid drugs.

We also believe that CMS significantly underestimated the size of the pharmacy overhead pool. In its June 2005 report to Congress, the Medicare Payment Advisory Commission (MedPAC) reported that non-drug hospital pharmacy costs were roughly 26 percent to 28 percent of total pharmacy costs. CMS proposed pharmacy overhead cost pool is equal to only 12.7 percent of the costs associated with packaged and separately-payable drugs – far less than the 26 to 28 percent estimated to be attributed to pharmacy services and handling. In addition, CMS analysis does not include the substantial number of drugs that do not have HCPCS codes or ASPs, yet have significant pharmacy service and handling costs.

CMS' analysis also does not take into consideration the costs of a possibly significant number of packaged drugs with HCPCSs and ASPs that hospitals have simply reported under an incorrect revenue code. We have learned that some hospitals, against the guidelines published by the National Uniform Billing Committee (NUBC), report detailed HCPCS drug information in revenue code 0250. Currently, NUBC guidelines state that revenue code *0250 General Classification of Pharmacy* does not utilize HCPCS reporting. By contrast, the revenue code *0636 Drugs Requiring Detail Code* is intended to be the location where such detailed HCPCS drug reporting occurs. When hospitals report detailed HCPCS under revenue code 0250, often the detail will not print out on the bill, or if it does print out, the Medicare contractor will return the claim to the provider. Either way, CMS will not receive the HCPCS code level information for these packaged drugs to use in establishing the pharmacy overhead cost pool. **The AHA recommends that CMS describe the NUBC guidelines, and encourage hospitals to report HCPCS codes for both separately payable and packaged drugs under the correct revenue code, 0636, noting how this will have an effect on the future pot of money available for allocation.**

Another problem with the CMS methodology is that it incorporates data from hospitals that participate in the 340B drug discount program. 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. When the 340B hospitals are excluded from CMS analysis, the mean unit cost rises to ASP plus 3 percent from ASP minus 2 percent. While the 340B program was not intended to harm other hospitals' ability to provide care by reducing their Medicare reimbursement, the inclusion of data from 340B hospitals is a growing problem as the numbers of participating hospital sites increased dramatically over the last several years and will grow further if pending health care reform legislation is enacted.

Having reviewed a number of flaws in CMS' methodology, we believe that CMS should abandon its current approach and default to the other option provided by Congress – to pay for separately covered outpatient drugs at a minimum of at least the rate paid in physicians' offices, ASP plus 6 percent (or the CAP rate, as applicable.) If CMS decides not to pay at ASP plus 6 percent, then alternatively AHA urges CMS to exclude claims data from 340B participating hospitals in calculating the acquisition cost for all separately payable drugs and then apply the redistributed pharmacy overhead amount.

PROPOSED OPPS PAYMENT FOR DRUG ADMINISTRATION

As part of its standard annual review, CMS analyzed the assignments of drug administration CPT codes into the five-level APC structure and, based on the results of this review, proposes to continue a five-level APC structure. Further, CMS proposes several minor reconfigurations of the APCs to account for changes in HCPCS code-specific median costs resulting from updated 2008 claims data, the most recent cost report data, and the 2010 drug payment proposal. **The AHA recommends that CMS continue to evaluate the five-level APC structure on a yearly basis.**

OPPS: HOSPITAL VISITS

Since April 2000, hospitals have been using the American Medical Association's (AMA) CPT evaluation and management (E/M) codes to report facility resources for clinic and 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 (AHIMA) 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.

Proposed Codes and Coding Policy for 2010

Since the publication of the 2008 outpatient PPS/ASC final rule with comment period, CMS has examined the distribution of clinic and Type A ED (open 24/7) visit levels based upon available, updated 2007 claims data. CMS continues to observe a normal and stable distribution of clinic and ED visit levels in hospital claims.

Clinic Visits, New Versus Established. For 2009, 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. Beginning in 2009, CMS refined the definition of “new” and “established” patients to reflect whether the patient was registered as an inpatient or outpatient of the hospital within the past three years.

For 2010, CMS proposes to retain the refined definitions of “new” and “established” patients, and to continue calculating median costs for clinic visits under the OPSS using historical hospital claims data. **As stated in our comments on previous OPSS proposed rules, the AHA continues to recommend that CMS remove the distinction between new and established patient clinic visits.**

While 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. **Clinic visits should be recognized on the basis of hospital resources utilized during a specific visit and 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 the distinction between new and established patients.**

Proposed Treatment of Guidelines for 2010

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 its 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.

Since the implementation of the OPSS, the AHA has advocated for 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), each hospital's reported E/M levels reflect a different aspect of hospital resource utilization and are not comparable.

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. **As stated in previous comment letters, the AHA urges CMS to adopt national guidelines for hospital ED and clinic visits.**

The reasons identified in previous comments from the AHA, as well as from others, regarding the need for national guidelines remain valid. In order to "play by the rules," a clear and detailed set of rules is needed. This becomes a more acute concern as CMS rolls out a national Medicare Recovery Audit Contractor program and a Medicaid Integrity Provider Audit program. We continue to be concerned that using the CPT E/M codes with meanings and guidelines different than the AMA's CPT descriptors and guidelines place our members at risk for violations of the Health Insurance Portability and Accountability (HIPAA) code set standards rule.

In the August 9, 2002 OPSS 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.

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 into 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 the AHA Central Office on HCPCS.

If national guidelines are adopted for hospital visit coding, we strongly urge CMS to do so no later than CY 2011. Given the ICD-10-CM and ICD-10-PCS compliance date of October 1,

2013, it would be extremely burdensome, if not impossible, for hospitals to implement all these coding changes concurrently.

Finally, given CMS' apparent lack of interest in adopting national guidelines, the AHA will reconvene the AHA/AHIMA Coding Expert Panel to update the 2003 Recommendation for Standardized Hospital Evaluation and Management Coding of Emergency Department and Clinic Services model. The revised recommendations from this expert panel will be submitted 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. We are hopeful that CMS will be engaged in our AHA/AHIMA coding expert panel and supportive of our recommendations to the AMA CPT Editorial Panel.

OUTPATIENT PPS: PARTIAL HOSPITALIZATION

For 2010, CMS proposes to continue to use two separate APC payment rates for partial hospitalization program (PHP) services – one for days with three services (APC 0172) and one for days with four or more services (APC 0173). Although the agency proposes to continue using only hospital-based PHP claims data to determine the payment rates for these APCs, CMS requests comments on the possibility of returning to its pre-2009 policy of using both community mental health center (CMHC) and hospital-based data to develop the payment rates for the final rule.

The AHA strongly recommends that CMS continue to use only hospital-based data to set payment rates in 2010. In our comments on the 2009 OPSS proposed rule, we described the results of an analysis that the AHA and the National Association of Psychiatric Health Systems conducted using three years of PHP data, including data from 2003, 2004 and 2006. That data told a compelling story and led to our recommendation that hospitals be paid for PHP services using only hospital-based data. This story has not changed, and the reasons we cited last year that supported the use of only hospital-based data to set the PHP payment rates continue to apply. These include:

- *Community Mental Health Center 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 reported its suspicions 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.

By 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 Vision 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 70 percent of hospital-based PHP days reporting four or more units of service. By contrast, CMHCs have been reducing the intensity of their services over the last several years and, therefore, not living up to CMS' expectations for PHP services. In 2008, 67 percent of CMHC PHP days had three or fewer services.
- *Financial Impact and Concern about Further Rate Reductions.* Based on the data presented in the proposed rule, if CMS were to use both hospital-based and CMHC data to calculate PHP payments, payment for APC 0173 would decline by 12 percent from its 2009 payment rate and payments for APC 0172 would decline by 16 percent. The AHA is concerned that any further reduction in rates could threaten access to PHP services in many states. This is because 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.
- *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 in a single day at the payment for a day of partial hospitalization, which CMS considers to be the most intensive of all outpatient mental health treatment. Until CMS made the decision in 2009 to exclude CMHC data from the calculation of the PHP payment rates, CMHCs, who are providers not eligible to provide the Mental Health Composite APC 0034 or other non-PHP hospital outpatient services, were controlling and dragging down the payment rate for these hospital outpatient services. The AHA strongly believes that hospital data should be used to set the payment rates for hospital services. We remain concerned that returning to the use of 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.

In addition, as CMS notes, there were significant changes made to PHP policy and payment in 2009, and it would be unwise to further reduce the payment rates for the two APCs without a better understanding of the impact of these changes. For all of these reasons, we urge the agency to continue to use only hospital PHP data to set payment rates for hospital-based PHP services in 2010.

OUTLIER RECONCILIATION

In the 2009 OPSS final rule, CMS adopted a process to reconcile hospital outlier payments at cost report settlement for services furnished during cost reporting periods beginning in 2009. CMS notes in the 2010 proposed rule that the agency does not adjust the fixed-dollar threshold amount of total OPSS payment set aside for outlier payments for reconciliation activity, noting that the predictability of the fixed-dollar threshold is an important component of a PPS.

However, with Medicare's focus moving towards retrospective review of payments, perhaps it is time for CMS to reconsider this policy and adopt a policy of transparency. **To help inform such a reconsideration, the AHA recommends that CMS use its annual rulemaking to begin to regularly report on the reconciliation activity that has occurred, including the aggregate amounts recovered by provider type and region.** If the recovered outlier amounts are significant, CMS should consider adjusting the fixed-dollar threshold or amount of total OPSS payment set aside for outlier payments to account for this reconciliation activity.

CARDIAC REHABILITATION, PULMONARY REHABILITATION AND INTENSIVE CARDIAC REHABILITATION SERVICES

In accordance with provisions in MIPPA, CMS proposes to establish a new benefit and OPSS payments for CR, PR and ICR services for beneficiaries with chronic obstructive pulmonary disease, cardiovascular disease and related conditions, effective January 1, 2010.

Supervision. As stated previously, the AHA recommends that CMS reconsider its decision to limit supervision of CR, PR and ICR services to physicians only. **We believe that the language of MIPPA does not preclude allowing NPPs to provide direct supervision, and we recommend that CMS do so, consistent with CMS' proposal for other outpatient therapeutic services.**

Payment for Cardiac Rehabilitation Services. The proposed payment for CR services does not reflect their costs when considering the new services that MIPAA mandates and that CMS is proposing to incorporate into the existing CR codes. In the 2009 OPSS final rule, CMS indicated that in response to a recommendation from RTI International, it would add a new nonstandard cost center for CR for 2010 in order to better capture cost report information for this service. Instead, in the 2010 OPSS rule, CMS proposes to postpone this change until 2011. **The AHA recommends moving forward with the methodology adjustment as soon as is feasible to ensure accurate cost data are available in the future.**

Cardiac Rehabilitation Program Delivery Models. The AHA supports recommendations from the American Association of Cardiovascular and Pulmonary Rehabilitation and the American College of Cardiology that CR programs be given reasonable flexibility to determine the most effective delivery model within appropriate limits. They recommend an allowance for up to a maximum of 36 medically supervised sessions delivered over a maximum of 36 weeks. This

gives programs the flexibility to determine the frequency and duration of medically supervised sessions that would be most beneficial to each individual patient with no greater financial burden to CMS.

Pulmonary Rehabilitation: Sessions. The proposed rule establishes a limit of 36 “sessions” of PR with each billable session defined as one hour. However, this is an erroneous interpretation of the clinical literature and published professional guidelines – the term “sessions” is not synonymous with “hours.” A typical PR session may last two to three hours, very rarely just one hour. This 36-hour payment cap is contrary to existing CMS policy found elsewhere related to PR services. For instance, the lung volume reduction surgery national coverage decision mandates a minimum of 44 hours of rehabilitation, up to a maximum of 60 hours, in two-hour minimum increments.

The AHA recommends that CMS adopt a policy of covering up to 72 hours of pulmonary rehabilitation, based on the individual’s medical necessity. We also recommend that CMS not finalize the proposed cap of one hour of billable PR per day, as this is not based on any clinical limitation appearing in the literature. Providers of PR services must retain the flexibility to design their programs in an efficient manner that provides effective rehabilitation services in accordance with established clinical practice guidelines and accepted standards of care.

Pulmonary Rehabilitation: Payment. CMS proposes to create one new Level II HCPCS code, GXX30 (Pulmonary rehabilitation, including aerobic exercise (includes monitoring), per session, per day) for hospitals to report and bill for the services furnished under a PR program. This would replace the current G-codes for PR, G0237-G0239. Given the lack of hospital OPPS cost data for this newly defined service, CMS proposes to temporarily assign this code to New Technology APC 1492, which would establish a payment rate for PR of \$15 per hour. This rate is similar to the 2010 “nonfacility” practice expense payment level proposed for PR under the physician fee schedule proposed rule.

The AHA believes that CMS’ calculations are flawed. The new GXX30 code represents one hour of service, while the codes it replaces represent 15-minute service increments. Currently G0237-G0239 pay at approximately \$27 for a 15-minute increment. Replacing these codes with a single code that has less than one-seventh the value for a full hour of service is unreasonable. **We recommend that CMS assign PR to a higher level new technology APC in order to provide a payment level that is more consistent with the current payment level for PR services.**

KIDNEY DISEASE EDUCATION

In establishing a proposed payment rate for kidney disease education (KDE), CMS cross-walked this service to medical nutrition therapy because kidney education is similar to medical nutrition therapy in the individual and group settings. However, CMS did not correctly match up the time for the services. A KDE service delivered by a physician, or other qualified person, is defined as

a 60-minute service compared to the 15-minute service (30 minutes for a group) CMS used to pay for the service delivered by a nutritionist. Consequently, a 60-minute kidney education session is proposed to be paid at the same rate as a 15-minute nutritional assessment. This error should be corrected so that the times and the resulting total payments for the encounter are the same for kidney education and nutrition. It seems inconceivable that the value of a physician or physician assistant or masters-prepared nurse should be set at one-fourth of the value of a nutritionist's time.

Therefore, the AHA recommends that for 2010, the payment for kidney education services related to the care of chronic kidney disease (individual per session) which is defined as having a duration of 60 minutes, should be made at four times the payment rate for medical nutrition therapy, initial assessment and intervention (CPT 97802 Medical nutrition therapy). For 2010, the payment rate for chronic kidney disease education (group per session), which is defined as 60 minutes, should be made at two times the payment rate for CPT 97804 medical nutrition (group).

AMBULATORY SURGICAL CENTER ISSUES

ASCs: Quality Data Reporting

The Tax Relief and Health Care Act of 2006 mandated that the Secretary include ASCs in the outpatient quality reporting program. In the 2008 and 2009 OPPS/ASC final rules, CMS stated its intent to implement quality reporting for ASCs in a future year. However, in the 2010 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 a disservice to patients that they have access to surgical quality information from hospital outpatient departments, but the same level of transparency from ASCs is unavailable to them.

ASCs: Cost Reporting

Under the methodology of the revised ASC payment system, ASC cost information is not used to set and revise ASC payment rates. Instead, CMS relies on the relativity of hospital outpatient costs developed for the OPPS. In light of MedPAC's recommendation that ASCs should be required to submit cost data to the Secretary to allow for an effective evaluation of the adequacy of the ASC payment rates, CMS is seeking comment on the feasibility of ASCs submitting cost information.

The AHA continues to urge CMS to require ASCs to begin to routinely report cost data to allow for future validation of the relative appropriateness of ASC payment weights and rates. This could be accomplished through implementing an ASC cost-reporting system or through the periodic collection of ASC cost data at the procedure level.

June 1, 2009

VIA ELECTRONIC AND U.S. MAIL

Jonathan Blum
Director
Center for Medicare Management
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW, Room 314G
Washington, DC 20201

Re: Physician Supervision for Hospital Outpatient Therapeutic Services

Dear Mr. Blum:

Thank you for arranging our recent meeting with your staff on the issue of physician supervision for incident-to outpatient hospital therapeutic services. The meeting was a productive conversation about whether from a clinical perspective direct supervision by a physician is necessary for these services. In our view, a different policy that reflects the true clinical needs of patients and the practical availability of physicians to supervise the services would better serve the Medicare program and its beneficiaries.

Separately, our members remain very concerned about certain CMS statements from the 2009 OPPS rulemaking that have the potential to subject hospitals to substantially heightened and unwarranted enforcement scrutiny. As the agency considers next steps related to its policy, we strongly urge CMS to take immediate steps to mitigate the new and inappropriate enforcement risks that the troubling CMS statements have created.

I. Background

At issue is the 2009 OPPS rulemaking's characterization that a "restatement and clarification" of the physician supervision policy was necessary because there may have been a "misunderstanding" about what, if any, level of physician supervision was required for incident-to outpatient therapeutic services. (73 *Fed.Reg.* 68,702.) The rulemaking further states that "[i]t is our expectation that hospital outpatient therapeutic services are provided under direct supervision of physicians in the hospital and in all provider-based departments of the hospital, specifically both on-campus and off-campus departments of the hospital."

Our hospitals believe strongly that the 2009 OPPS rulemaking was a significant policy change for certain settings, not a restatement or clarification of existing policy. The record is clear that "direct supervision" by a physician has been a requirement since 2001 only for incident-to outpatient therapeutic services furnished in a department that is located off the hospital's

campus. We believe the record is equally clear that, prior to January 1, 2009, direct supervision by a physician was not required for incident-to outpatient therapeutic services furnished in a hospital or in a department located on a hospital's campus. The 2001 OPSS final rule supports our view and could not be more specific: "[o]ur proposed amendment of §410.27 to require direct supervision . . . does not apply to services furnished in a department of a provider that is located on the campus of the hospital." (65 *Fed. Reg.* 18,525.) This same policy position was adopted for services furnished "in the hospital." For CMS now to say otherwise about past time periods opens up the entire hospital community to misplaced enforcement scrutiny, including by potential *qui tam* relators, for services furnished in a hospital or on a hospital's campus before January 1, 2009.

II. The 2009 OPSS Preamble Exposes Hospitals To Significant Enforcement Scrutiny

Through our ongoing dialogue with CMS, we learned that an assumption made by CMS in 2001 may be the root cause for the concerns related to the policy. During the 2001 rulemaking, CMS assumed that when services are furnished "on the premises" (a location description that CMS determined included both in a hospital and on a hospital's campus), "physician supervision is always at hand." (63 *Fed.Reg.* 47,593.) The stated assumption, however, does not specify any particular level of physician supervision that CMS expected to be available. As a result, most hospitals interpreted the policy to require only "general supervision" by a physician for services furnished in a hospital or on a hospital's campus.

It now seems that CMS had an expectation that "direct supervision" was the applicable standard adopted at that time. However, the extensive regulatory analysis contained in our previous letter shows that while physician supervision was required, the 2001 rulemaking does not support a policy of direct supervision by a physician for services furnished in a hospital or on a hospital's campus, which is what CMS now desires. The 2009 rulemaking, in fact, is the first time the direct supervision by a physician requirement was applied to all settings for incident-to outpatient therapeutic services.

Because of CMS's statements about the 2009 rulemaking being a "restatement and clarification" of policy, the enforcement risk for periods prior to the 2009 rulemaking statements has now increased exponentially. By asserting that since 2001 the agency's policy has required direct supervision by a physician, CMS now exposes hospitals to potential recoupments and whistleblowers who can claim that a hospital did not have appropriate direct physician supervision arrangements in place in some or all of its affected departments dating back to 2001.

Such claims are often attractive to whistleblowers because of the lucrative amounts of Medicare reimbursement at issue, which is determined based upon the nature of the direct physician supervision requirement, its impact on the payment status of all services furnished to Medicare

beneficiaries in that department, and the construct of the penalty and damages provisions of the federal False Claims Act.

III. CMS Should Withdraw Immediately Its 2009 Preamble Statement Regarding Restatement and Clarification of 2001 Policy

Hospitals' concerns related to the enforcement scrutiny are real and CMS's statements currently leave hospitals exposed. We urge CMS to take quick action to communicate to the field on the status of the policy and its history. It seems clear that the CMS's expectations related to this policy were not fully appreciated and understood by hospitals, and one of the key reasons for that appears to be the unclear and imprecise drafting of prior policy discussions.

We believe it is in the best of interests of CMS, hospitals, and patients to revisit the policy, hopefully in the context of the 2010 OPSS rulemaking. In doing so, we hope to find an acceptable approach which best serves patients from a quality perspective while also properly balancing other realities, such as the clinical need for, and availability of, physicians to provide supervisory services. However, the potential for an explosion of enforcement scrutiny emanating from CMS's characterization of the new policy as a "restatement and clarification" could easily affect the ability to achieve that goal in a meaningful and non-adversarial way.

Therefore, we urge CMS to immediately acknowledge the field's concerns about the ambiguity and uncertainty around this policy, and to recognize that the agency's expectations for the policy were not communicated clearly in the 2001 rulemaking. We believe this could best be accomplished by rescinding Transmittal 101, Change Request 6320, Pub. 100-02 [Jan. 16, 2009].) Also, this can be communicated as part of the 2010 OPSS rulemaking preamble discussion. We suggest CMS use the following language in all related communications:

Following publication of the 2009 final rule, we learned of significant disagreement over whether Medicare payment policy has required since 2001 that incident-to outpatient therapeutic services furnished in a hospital or on a hospital's campus be provided under the direct supervision of a physician. As we stated in the 2009 preamble, Medicare policy is clear that physician supervision is required. However, upon closer review of earlier rulemaking discussions about specific levels of physician supervision and the settings to which they would apply, we now believe statements in the 2001 preamble appear to be inconsistent with our 2009 preamble characterization that we were merely restating and clarifying the 2001 policy. Many hospital and physician groups have written us expressly stating this view and we recognize the merits of these concerns, as well as the need to work with providers, patient groups and others to establish appropriate policy regarding physician supervision for outpatient therapeutic

services. Therefore, we invite public comment on this policy going forward, and withdraw our characterization, expressed in the 2009 preamble, that policy requiring direct physician supervision for therapeutic services other than those furnished in off campus departments was a restatement and clarification of existing policy.

* * * * *

Thank you for your willingness to work with us on this important issue. We would appreciate the opportunity to meet with you directly to further discuss our concerns about the possible enforcement impact of the 2009 preamble discussion.

Sincerely,

Association of American Medical Colleges
American Hospital Association
Federation of American Hospitals
National Association of Psychiatric Health Systems

April 14, 2009

VIA ELECTRONIC AND U.S. MAIL

Jonathan Blum
Director
Center for Medicare Management
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW Room 314G
Washington, DC 20201

Re: Physician Supervision for Hospital Outpatient Therapeutic Services

The undersigned organizations write to request that the Centers for Medicare & Medicaid Services (CMS) withdraw or delay the recent policy change regarding physician supervision of hospital outpatient therapeutic services as described below, and that it immediately instruct contractors that no enforcement actions should be initiated or pursued until the issues raised in this letter are addressed. The policy announced in the 2009 outpatient prospective payment system (OPPS) final rule, published on November 18, 2008, requires a physician privileged by the hospital to provide supervision to be physically present in the outpatient department at all times that outpatient therapeutic services are furnished, regardless of whether the services are furnished in the hospital, on the hospital campus or off-campus. This represents a significant change in Medicare payment policy. (*See 73 Fed. Reg. 68,702.*)

CMS' intent to revisit and alter this policy – identified by CMS as a “clarification” – was not clear in the 2009 OPPS proposed rule. There was a clear lack of effective and adequate notice about the CMS policy change, which as a result, affected the opportunity to comment on the proposal. Therefore, many in the field missed the opportunity to address the substantial impact this policy change would have on providers and physicians. The significance of this policy change became clear in January 2009 only as a result of an Open Door Forum call and the issuance of a revised Medicare manual provision well after the 2009 OPPS final rule was issued. Since that time, the specifics of the new policy have caused great concern due to the negative effects it would have on both hospitals and physicians, which are summarized in this letter.

We urge CMS to schedule a Special Open Door Forum or Town Hall meeting where affected providers can provide feedback to CMS about the impact of this new policy. Then, CMS should publish another discussion of the issue, including any proposed changes, in the 2010 OPPS proposed rule and offer alternate solutions.

If CMS decides not to revisit this onerous new interpretation, the agency still should provide for a delayed effective date. There are two reasons such a delay is necessary: (1) the agency did not provide adequate time for hospitals to modify their operations to be compliant with this new

policy by the January 1, 2009 effective date, and (2) this change was characterized in the *Federal Register* as a “restatement and clarification,” thereby causing many affected parties to fail to understand its significance or to provide adequate comments. The Agency also should impose an enforcement moratorium because of the steps hospitals and physicians need to take to achieve compliance for on-campus provider-based departments. If CMS objects to revisiting the policy in the 2010 OPPTS rulemaking, the agency nevertheless should provide a more robust explanation of why the new policy is necessary.

The new policy places a considerable burden on hospitals, requiring them to engage more physicians for direct supervisory coverage without a clear clinical need. This change comes at a time when relationships between physicians and hospitals are changing substantially and physician shortages in various specialties continue. It presents an issue of special concern for critical access hospitals (CAH) and for communities in which the shortage of physicians is especially severe. It may lead to patient access problems if hospitals are forced to discontinue certain outpatient services or shy away from opening new ones. The *Federal Register* discussion provides scant rationale for the new policy or any indication of whether other alternatives were considered. Therefore, it remains unclear as to why this change in policy is necessary from a clinical perspective.

I. Background

Currently, Medicare pays for outpatient therapeutic hospital services furnished “incident to” a physician’s service. (Social Security Act § 1861(s)(2)(B).) Medicare regulations set three basic conditions of payment for hospital incident to services: (1) services furnished by or under arrangement made by a hospital; (2) as an integral though incidental part of a physician’s service; and (3) furnished in the hospital or at a department of a provider, as defined in §413.65(a)(2), that has provided-based status. (42 C.F.R. §410.27(a)(1)(i)-(iii).)

CMS has addressed Medicare payment policy for incident to services in hospital outpatient departments at various times over the years. In 1998, CMS (then the Health Care Financing Administration) explained that “as a matter of policy, we require that the services and supplies be furnished on a physician’s order by hospital personnel and under a physician’s supervision.” (63 *Fed. Reg.* 47,593.) At the time, the Medicare Intermediary Manual (“MIM”) served as the source of this policy and did not require a specified level of physician supervision for payment of incident-to hospital services. (See MIM § 3112.4(A).) Specifically, the MIM provided only that “[t]he services and supplies must be furnished on a physician’s order by hospital personnel and under a physician’s supervision.”

The 1998 proposed rule stated that “[w]hen ‘incident to’ services are furnished on hospital premises, we assume the physician supervision requirement to be met because staff physicians would be present nearby within the hospital.” Further, the rule states that CMS equates “the location of the hospital outpatient department or hospital clinic within the hospital’s walls, or their co-location on the same campus, with being ‘on the premises,’ and we assume physician supervision is always at hand.” (63 *Fed. Reg.* at 47,593.)

Medicare policy did not specify a level of required physician supervision for incident to hospital outpatient services until this 1998 proposed rule, when CMS proposed a regulatory change to

require direct physician supervision for services furnished in a department or clinic “offsite and that is not on the hospital premises.” The scope of the proposed policy was decidedly narrow due to CMS’ clear statement that “on the premises of the hospital” included services furnished within the hospital’s main buildings and in any department or clinic co-located on the same campus as the hospital. Thus, the generally held view of this proposal by the hospital and physician communities was that it only imposed a direct supervision requirement for off-campus provider-based entities only. CMS did not express the same concerns about services rendered in hospitals and in on-campus provider-based departments, and therefore those sites of service remained subject only to the policy requirement of “under a physician’s supervision.”

The 2001 OPSS final rule fully supported the field’s view. In adding subsection (f) to 42 C.F.R. § 410.27, CMS sought to require direct physician supervision as a condition of payment for hospital outpatient incident to services rendered in provider-based departments. In the preamble, CMS drew a narrow application when it stated unequivocally that “[o]ur proposed amendment of §410.27 to require direct supervision . . . does not apply to services furnished in a department of a provider that is located on the campus of the hospital.” (65 *Fed. Reg.* 18,525.) Notably, the 2001 OPSS final rule did not impose any specific supervision requirements for hospital outpatient incident to services furnished in the hospital. Therefore, the regulation did not then – and does not now – require any specific level of supervision for outpatient therapeutic services furnished in the main buildings of a hospital or on a hospital campus.

Based on these pronouncements by CMS, hospitals have long believed that direct physician supervision is required only for hospital outpatient incident to services furnished in off-campus provider-based departments. Incident to services rendered in hospitals and at on-campus provider-based departments are required to be furnished under a physician’s supervision, although that supervision did not rise to the level of direct supervision as the term is defined in the incident-to regulations governing the physician office setting (42 C.F.R. §410.32(b)(3)(ii)) and the outpatient hospital setting (42 C.F.R. §410.27(f)).

In 2008, CMS revisited the scope of its direct physician supervision policy in the 2009 OPSS rulemaking. The 2009 OPSS final rule states that there may have been a “misunderstanding” about what, if any, level of physician supervision is required for incident to services furnished in a hospital or an on-campus provider-based department, and that a “restatement and clarification of the policy” was necessary. (73 *Fed. Reg.* 68,702.) In addressing the apparent misunderstanding, CMS stated “[i]t is our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based departments of the hospital, specifically both on-campus and off-campus departments of the hospital.”

CMS has since memorialized this “expectation” in section 20.5.1 of the Medicare Benefit Policy Manual. (*See* Transmittal 101, Change Request 6320, Pub. 100-02 [Jan. 16, 2009].)

Furthermore, the policy has gone beyond previous discussions regarding direct physician supervision in setting a strict physician proximity standard that would require the physician supervising the outpatient therapeutic service to be physically present in the provider-based department, regardless of whether the services are provided on campus or off campus, at all times that services are furnished. This new policy represents a major change for outpatient

hospital therapeutic services furnished in the hospital and on-campus provider-based departments.

II. CMS Should Withdraw the New Payment Policy or, at a Minimum, Delay the Effective Date

The 2009 OPPTS final rule discussion characterizes CMS' new policy on physician supervision for hospitals and on-campus provider-based departments as a "restatement and clarification" of existing policy. In reality, as demonstrated above, the final rule represents a significant change in policy for certain sites of service, such as outpatient infusion clinics and outpatient psychiatric facilities.

The undersigned organizations recommend that CMS immediately withdraw this onerous and unnecessary new policy. If CMS is unwilling to do so, then at a minimum, we urge CMS to delay the effective date for at least a year to allow hospitals to bring their on-campus arrangements into compliance. At the same time, CMS should direct all Medicare contractors to refrain from initiating or pursuing any enforcement actions based on this new policy until CMS provides additional direction. Given the significance of the changes, hospitals and physicians should be afforded ample time to make operational modifications when necessary, given that compliance with the new policy cannot be achieved immediately. The sixty-day notice before the policy's effective date was insufficient for hospitals to find and enter into arrangements with physicians to provide direct supervision in the additional sites of service required by the new policy. As a result, many hospitals now face a period of potential non-compliance while they seek to find physicians to provide direct supervision in on-campus provider-based departments.

Likewise, if CMS is unable to immediately withdraw this problematic policy, a delay also will allow the agency time to consider the suggestions made in this letter, such as holding a public meeting and engaging in further discussion in the 2010 OPPTS rulemaking process. Even if CMS ultimately decides not to revisit the policy, a delayed implementation date and parallel enforcement moratorium is nevertheless appropriate to allow hospitals and physicians to make necessary modifications to existing on-campus provider-based department arrangements.

III. CMS Should Seek Additional Public Input Before a New Policy is Implemented

It is unclear why CMS changed this policy. As stated above, the 2009 OPPTS final rule explains that CMS is concerned that there may have been a misunderstanding about what, if any, level of physician supervision is required for incident-to services furnished in a hospital or an on-campus provider-based department. (73 *Fed. Reg.* 68,702.) Because of this purported misunderstanding, CMS announced its "expectation" that direct physician supervision is a payment condition for incident to hospital outpatient therapeutic services furnished in the hospital and in all provider-based departments of the hospital, including on-campus and off-campus departments of the hospital. CMS argues that this "expectation" is rooted in longstanding Medicare policy, which it outlines in the CY 2009 OPPTS final rule's preamble.

This "expectation" is not supported by any regulation or previous policy statements related to services furnished in a hospital or on-campus provider-based departments. For incident to services furnished in the hospital, neither the governing regulation nor any other CMS policy has

previously imposed a direct physician supervision requirement. Although the “expectation” included in the 2009 OPSS rulemaking for services furnished in the hospital is not authorized by the governing regulation, CMS did not seek to change that regulation to properly implement this significant policy change. In our view, a regulatory change would be necessary to effectuate the new policy applicable to services furnished “in the hospital.”

For provider-based departments located on a hospital’s campus, the 2001 OPSS final rule unequivocally states that the direct supervision requirement does not apply. (65 *Fed. Reg.* 18,525.) This statement leads to the conclusion that the “expectation” is really new policy for sites of service other than off-campus provider-based departments.

In the 2009 OPSS final rule, CMS suggests that lack of direct physician supervision would be considered a “quality concern.” (73 *Fed. Reg.* 68,703.) Beyond this statement, CMS offers no evidence to support the assertion that quality is affected at these sites of service when there is no direct supervision. If quality is one of the reasons for imposing this new requirement, then CMS must make available the data that supports this contention.

Additionally, none of the sources CMS identifies as longstanding policy support for this expectation specifically mention, let alone require, direct supervision. Instead, “under a physician’s supervision” has been the operative standard. Clearly, this does not rise to the level of direct supervision. Furthermore, because direct supervision is one of three specified levels of physician supervision in 42 C.F.R. § 410.32, it is difficult to understand how long standing Medicare policy supports the expectation of direct supervision (over general or personal supervision) when the 2009 OPSS rulemaking was the first time that such terminology was used for sites other than off-campus provider-based entities. More telling, CMS refers to the changing landscape for hospital services caused by new technology and practice patterns, which seems to be an impetus for CMS’ new policy now seeking a more specific level of physician supervision.

It is unclear whether CMS considered alternative approaches for changing its physician supervision policy. One possibility could be a policy that is similar to the outpatient diagnostic services policy, which acknowledges that different outpatient therapeutic services warrant different levels of supervision by requiring one of three levels of supervision (*i.e.*, general, direct, or personal). CMS should re-visit the policy in the 2010 OPSS rulemaking and seek comment on this approach and other possible alternatives. If concerns lie with the framework of certain on-campus arrangements and the ready access of a physician supervisor, modifications to CMS’ provider-based policies may address them.

In sum, there are other alternatives to CMS’ across-the-board direct physician supervision policy for hospital outpatient therapeutic services, and those alternatives should be more fully vetted before CMS decides upon a final policy. The new policy will affect many existing hospital services and challenge hospitals to produce sufficient physician supervisors to keep all existing outpatient service lines open in order to avoid access problems for patients. It will limit physicians in their ability to provide patient care if they must spend time providing direct supervision of services that to date have been provided effectively without such supervision. The impact will be particularly severe for small or rural hospitals, such as CAHs, which are often the only source of outpatient hospital services within many miles and which are in locations

Jonathan Blum
April 14, 2009
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which may have only one or two physicians in the entire community. CMS should take into account all of these factors in its quality of care cost/benefit analysis.

We respectfully urge CMS to withdraw the new policy and return to the former policy long understood by the hospital and physician communities. If CMS is unwilling to do so, then we urge the agency, at a minimum, to immediately impose a delay in the effective date of this new policy, to suspend enforcement, and to reopen the new policy for additional public input and consideration of alternatives. A Special Open Door Forum or Town Hall meeting would be an important first step for the agency to ensure it provides the hospital and physician community with the opportunity to provide full feedback on the new policy's impact. Following this public discussion, CMS should reopen the discussion of the merits of this policy change for further public comment during the 2010 OPSS rulemaking process, including a discussion about whether such a change in policy is clinically warranted. In doing so, CMS should consider alternate approaches to addressing the agency's concerns. Under any scenario, CMS should explain in more detail the reasons for making this policy change.

* * * * *

Thank you for your consideration of our letter. We would appreciate the opportunity to meet with you soon to discuss our requests and related issues in more detail.

Sincerely,

Association of American Medical Colleges
American Association of Cardiovascular and Pulmonary Rehabilitation
American Hospital Association
American Psychiatric Association
American Society for Radiology Oncology
Catholic Health Association
Federation of American Hospitals
National Association for Medical Direction of Respiratory Care
National Association of Psychiatric Health Systems
National Rural Health Association
Premier
VHA Inc.