



**American Hospital  
Association**

Liberty Place, Suite 700  
325 Seventh Street, NW  
Washington, DC 20004-2802  
(202) 638-1100 Phone  
[www.aha.org](http://www.aha.org)

September 6, 2013

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1601-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

***RE: CMS-1601-P, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Quality Improvement Organizations; Electronic Health Records Incentive Program Regulations; (Vol. 78, No.139), July 19, 2013.***

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for calendar year (CY) 2014 hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) quality reporting programs; enforcement of direct supervision requirements in critical access hospitals (CAHs) and small, rural hospitals; quality improvement organizations (QIO); hospital value-based purchasing (VBP); and electronic health records (EHR) incentive program changes.

The AHA thanks CMS for posting corrected CY 2014 OPPS addenda and cost statistics and impact files as well as for extending the comment period to allow for more analysis from the AHA and other stakeholders. As a result, this will be the first of two comment letters that the AHA will send in response to the CY 2014 OPPS proposed rule. This letter addresses only those topics, including the topics listed above, which are not dependent on CMS's recently released data corrections. Our second letter, which will be sent before the end of the extended comment period granted in the Sept. 5 *Federal Register* corrections notice, will discuss the AHA's recommendations related to proposed changes in OPPS packaging, comprehensive ambulatory payment classifications (APCs) and hospital outpatient visit coding and payment.

**The AHA is disappointed that CMS intends to allow its contractors to begin to enforce the direct supervision requirements for outpatient therapeutic services furnished in CAHs and small, rural hospitals.** Imposing this policy in rural hospitals is not only unnecessary, but also



would result in reduced access to care for Medicare beneficiaries. We have attached a compilation of reactions from a few of these hospitals to demonstrate this very real concern. (See Attachment A).

We also include comments on other CMS proposals and requests for comment including: coding and payment for critical care services; proton beam therapy; fecal microbiota transplantation; collecting data on services furnished in off-campus provider-based departments of the hospital; the new Medicare condition of payment for “incident-to” outpatient therapeutic services; partial hospitalization program policies; the outpatient and the ASC quality reporting programs; hospital VBP; changes to the QIO regulations; and the EHR incentive program.

In brief, the AHA makes the following key recommendations:

- The AHA urges CMS to extend the direct supervision enforcement moratorium instruction for at least one more year in order to study the possible unintended consequences on Medicare beneficiary access to care and, at the same time, to develop policies that exempt CAHs and small, rural PPS hospitals from the requirement so that they can continue to offer high quality and safe health care services that meet the needs of their local populations.
- We urge CMS to use its regulatory authority to adopt changes to the supervision regulations, including:
  - adopting a default standard of “general supervision” by a physician or non-physician practitioner (NPP) for outpatient therapeutic services;
  - creating an exemption process using a provider advisory panel to identify those outpatient services risky and complex enough to require direct supervision;
  - ensuring that for CAHs, the definition of “direct supervision” is consistent with the CAH conditions of participation that allow a physician or NPP to present within 30 minutes of being called;
  - permitting NPPs to supervise cardiac and pulmonary rehabilitation services; and
  - holding hospitals and CAHs harmless from civil or criminal action because of CMS’s retroactive and erroneous reinterpretation of the “direct supervision” requirements for the period 2001 through 2014.
- We urge CMS to re-consider the potential impact on advanced imaging services that could result from the use of the new radiology cost-to-charge ratios (CCRs) in the outpatient setting and not adopt them for use in rate-setting in CY 2014.
- We recommend that CMS continue to use the device-to-procedure and the procedure-to-device edits as well as the nuclear medicine procedure-to-radiolabeled product edits.
- We recommend that CMS not adopt the cataract surgery outcome and endoscopy use measures in the outpatient quality reporting program because they are not yet tested for facility-level measurement and are not feasible for hospitals to collect.
- We appreciate CMS’s proposal to allow physicians who provide services in the outpatient departments of CAHs and have their services billed by the CAH under Method 2 to

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participate in the EHR incentive program in 2013 and urge CMS to act as quickly as possible to provide detailed guidance on how physicians can take advantage of this policy change.

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

Sincerely,

/s/

Rick Pollack  
Executive Vice President

Attachments

**AMERICAN HOSPITAL ASSOCIATION**  
**DETAILED COMMENTS ON THE PROPOSED RULE FOR CY 2014 HOSPITAL**  
**OUTPATIENT AND AMBULATORY SURGERY PPS AND QUALITY REPORTING**  
**PROGRAMS; QUALITY IMPROVEMENT ORGANIZATION REGULATIONS**  
**AND EHR INCENTIVE PROGRAM**

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## **DIRECT SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES**

CMS proposes to end, as of Dec. 31, 2013, its prohibition on Medicare contractors enforcing the direct supervision policy for outpatient therapeutic services furnished in CAHs and in small and rural PPS hospitals having 100 or fewer beds. For CY 2014, the agency proposes to require a minimum of direct supervision for all outpatient therapeutic services furnished in hospitals and CAHs, unless the service is on the list of services that may be furnished under general supervision or is designated as a nonsurgical extended duration therapeutic service.

**The AHA is extremely disappointed that CMS has not heeded the concerns voiced by CAHs and small, rural hospitals that imposing the agency's direct supervision policy is not only unnecessary, but would result in reduced access to care.** As we discuss in more detail below, AHA's members tell us that given the lack of adequate numbers of physicians and other health professionals in rural communities to provide direct supervision, hospitals would have no choice but to limit their hours of operation or close certain programs. The impact of CMS's proposal goes far beyond patient inconvenience. When a CAH or other small, rural hospital that is the only facility within many miles offering certain services, such as chemotherapy infusion and radiation therapy, curtails its service hours or eliminates a program, the sickest patients may find they have no choice but to travel further to receive their care at another facility. Others may decide the distance is too far to travel for services, such as cardiac or pulmonary rehabilitation, and conclude their treatments. Doing this may require them to return to the CAH or hospital and be considered a readmission, when their condition deteriorates.

**As noted and described in more detail below, the AHA strongly urges CMS to extend the enforcement moratorium instruction for at least one more year in order to study these possible, unintended consequences. At the same time, CMS should develop policies that exempt CAHs and small, rural PPS hospitals from the direct supervision requirement so that they can continue to offer high quality and safe health care services, such as chemotherapy and radiation oncology services, that meet the needs of their local populations.**

**Health Professional Workforce Shortages Continue in Rural Areas.** Health professions workforce shortages are exacerbated in rural areas, where communities struggle to attract and keep well-trained clinicians. Although 19.2 percent of the U.S. population lives in rural America, only 11.4 percent of physicians practice in rural locations. Recent Health Resources and Services Administration (HRSA)-sponsored research revealed that 77 percent of rural counties in the U.S. are designated as primary care health professional shortage areas (HPSAs). As the expanded coverage available under the *Patient Protection and Affordable Care Act* (ACA) begins to take effect in CY 2014, many are predicting increased demand for physicians and other qualified health professionals, especially those who provide primary care and comprehensive care for those with multiple chronic conditions, thus increasing the difficulty some regions will have in attracting needed physicians and NPPs.

In addition, according to the U.S. Department of Health and Human Services' (HHS) Rural Assistance Center, over the last 25 years, aging and migration patterns have changed the composition of the rural population. Both the elderly and immigrant populations are on the rise, dramatically affecting the demands for health care services in rural areas. In 2010, nearly 40 million people age 65 and over lived in the U.S. This number represents 13 percent of the U.S. population, or about one in every eight Americans. It is projected that by the year 2030, there will be about 72.1 million people age 65 and over, more than twice their number in 2000. The elderly make up 7.5 million of the 50 million people living in rural America (15 percent). While the percentage of elderly living in rural areas is only slightly higher than in urban areas, the share of the elderly rural population is growing. In one quarter of all non-metropolitan counties, the percentage of rural elderly already reaches 18 percent. Further, the elderly who live in rural areas face additional challenges, such as lack of transportation for medical appointments and lack of access to medical care.

The continued existence of CAHs and other small, rural hospitals in these communities is the result of a careful balancing of policies and practices to ensure access to essential and high-quality health care services. This includes the widespread use of telemedicine, carefully crafted and exercised nurse protocols and standing orders, and Medicare personnel conditions of participation and state licensing standards that effectively acknowledge health professions workforce challenges and are designed to preserve access to care in rural communities. Further, physicians and other health professionals who choose to practice in rural communities also have private practices or clinic responsibilities that are their primary obligation. With their own patient caseload, these clinicians have limited ability to be "immediately available" to provide supervision for hospital outpatient department services, particularly for those critical specialty services that cannot be supervised by a hospital emergency physician or NPP.

**Rural Hospital Response to CMS's Request for Comment.** The AHA solicited responses from CAHs and small, rural PPS hospitals regarding CMS's request for comments on the potential impact of its proposed direct supervision policy. Specifically, CMS asks about the potential impact on access to care and quality of care for specific services that could result from allowing the enforcement moratorium to end. The agency also wants to know the specific services for which CAHs and small, rural hospitals anticipate difficulty complying with the direct supervision policy, including specific factors that may contribute to the lack of available staff. A compilation of 11 hospital written responses to our request is attached to this letter (Attachment A). Below, we have distilled the key messages conveyed by these and other hospitals.

In general, what the AHA heard from rural hospitals is that the direct supervision requirement would be very difficult to implement because of the shortage of physicians in rural areas, and it would severely limit the types of services that rural hospitals can offer to their communities. CAHs and small, rural PPS hospitals are extremely concerned that ending the enforcement moratorium would have a significant negative impact on local patient access to care. They note that inadequate numbers of physician and NPP staff available to provide direct supervision would give their facilities no other choice but to limit the hours of operation for certain critical

services, including chemotherapy, intravenous infusion of antibiotics, cardiac and pulmonary rehabilitation, observation, blood transfusions and radiation oncology. This limitation could be extremely problematic for beneficiaries in rural areas because access to these services is already sparse. For example, according to 2011 AHA survey data, the most recent data available, only 35 percent of rural PPS hospitals and CAHs offered chemotherapy services; only 32 percent offered oncology services; and only 12 percent offered radiation therapy. Because hospitals operate on a 24/7 basis, arranging physician or NPP supervision would be particularly difficult during evening or weekend hours.

Some facilities said that they would stop offering certain services altogether due to the inability to find physicians or NPPs able or willing to abandon their private practices or clinic duties in order to provide direct supervision. These hospitals noted that the patients who would experience the greatest impact on access are most likely to be elderly and they are often both physically and financially vulnerable, making travel to other facilities to receive care difficult, if not impossible. There is a concern that some patients would elect to discontinue their outpatient care because of cost or inability to travel, resulting instead in additional hospital readmissions and increased Medicare spending.

Rural hospitals predict that enforcing the direct supervision rules would make it harder to recruit physicians to the rural area and make it less attractive for young people to go into rural medicine. As it is, recruiting both primary care and specialty providers to practice in rural areas is extremely difficult, and few – if any – physicians are on call to see patients on a 24/7 basis. Young physicians seek work-life balance, and many rural hospitals are not in a position to provide in-house or on-call coverage relief that meets the requirements of today's physicians. Thus, they would have to limit services that require direct supervision. For some small, rural hospitals, particularly very rural and frontier CAHs, recruiting qualified NPPs to provide direct supervision is as difficult as recruiting physicians. As described below, this is made more challenging by CMS's requirement that physicians and NPPs providing direct supervision must have a state license scope of practice and hospital-granted privileges that would permit them to perform the services they supervise.

Many of the hospitals emphasized that requiring direct supervision is impractical, unnecessary to deliver health care in rural communities and will not improve the quality of care. CMS has never presented evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision. The fact is that hospitals have been successfully providing outpatient therapeutic services under general supervision for many years without adverse results. Their nursing staffs are highly trained to handle most emergency situations and generally provide services based on protocols established by the hospital medical staff. In the rare instance in which something goes wrong that the on-site staff cannot handle, they have ready access to physicians by phone, telemedicine, or in person within a reasonable period of time. CAHs note that their conditions of participation require a physician or NPP to be physically present at the CAH within 30 minutes of being called for an emergency.

As noted above, given the potential for serious consequences to Medicare beneficiary access to care, the AHA strongly recommends that CMS extend the enforcement moratorium by at least one more year in order to further study such possible consequences. The time could also be used to develop and vet improved policy options, such as potentially creating quality measurement options, to further demonstrate the quality and safety of outpatient therapeutic services. In addition, we describe other options below that could address CAH and small, rural PPS hospital concerns while still satisfying CMS and hospitals' interest in ensuring the quality and safety of outpatient therapeutic services.

**The Path Forward.** We believe that fundamental changes are needed to support the ability of hospitals in rural communities to sustain access to care. Therefore, AHA continues to support changes that are contained in the *Protecting Access to Rural Therapy Services Act of 2013* (H.R. 2801/S. 1143). While this bill has not yet been enacted by Congress, we urge CMS to use its regulatory authority to adopt the changes in the bill. Specifically, CMS should:

- Adopt a default standard of “general supervision” by a physician or NPP for outpatient therapeutic services.
- Create an exemption process using a provider advisory panel to identify those outpatient services risky and complex enough to require direct supervision.
- Ensure that for CAHs, the definition of “direct supervision” is consistent with the CAH conditions of participation that allow a physician or NPP to present within 30 minutes of being called.
- Permit NPPs to supervise cardiac and pulmonary rehabilitation services.
- Hold hospitals and CAHs harmless from civil or criminal action regarding CMS's retroactive reinterpretation of “direct supervision” requirements for the period 2001 through 2014.

We contend that general supervision is a more reasonable standard for outpatient therapeutic services furnished in rural hospitals, and, as noted above, CMS has offered no evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision.

Other issues that have arisen as a result of CMS's direct supervision requirement are discussed below.

**Medicare Contractor Enforcement of Supervision Requirements.** We have heard concerns from a number of hospitals assessing how to come into compliance with the supervision requirements. These providers are worried about enforcement risk related to the ambiguities in CMS's definition of direct supervision, particularly the interpretation of the term “immediately available.” These hospitals are concerned that the policies and procedures they create and implement that are intended to satisfy the direct supervision requirements will be challenged,

second-guessed and rejected by CMS contractors, such as Medicare Administrative Contractors (MACs) and Recovery Audit Contractors (RACs).

Due to the vast differences among hospitals in terms of services offered, facility infrastructure, staffing and patient mix, the AHA appreciates that CMS has *not* created an objective measure of distance or time to satisfy “immediately available.” **We recommend that CMS actively discourage its contractors from establishing arbitrary time and/or distance standards for direct supervision. Instead, we urge the agency and its contractors to continue to allow hospitals to develop and apply reasonable and patient-focused supervision policies and practices within their own institutions, taking into consideration their unique patient mix, type of services offered, physical infrastructure and workforce limitations.** As long as these hospital supervision policies reasonably satisfy direct supervision requirements – appropriately balancing patient access and safety – and the hospital consistently applies its own policies, Medicare contractors should be instructed not to second-guess hospital policies.

**Clarification of Observation Services Supervision.** The AHA appreciates CMS’s clarification that the transition from direct to general supervision for observation services occurs only once during a patient’s stay in observation care, and not every time a new unit of observation is billed.

**Hospital Outpatient Payment (HOP) Panel Process.** In the CY 2012 OPPTS final rule, CMS established an independent review process that allows for an assessment and re-assignment of the appropriate supervision levels for individual hospital outpatient therapeutic services. We are pleased that CMS supports our view that this process and its outcomes fall clearly within the agency’s authority. That is, while Medicare covers hospital outpatient therapeutic services as “incident to” a physician’s service, the law does not mandate a specific level of supervision, but rather leaves this entirely within CMS’s regulatory discretion. The AHA and its members believe that there are numerous outpatient therapeutic services that could be furnished safely under general supervision, including all of the remaining non-surgical extended duration therapeutic services (NSEDTS), short duration services, minor surgical procedures and the recovery portion of certain surgical services after the patient has been cleared by the anesthesiologist.

**While the AHA continues to support the HOP Panel’s efforts, we do have concerns about the process and offer several recommendations to improve it. These are related to the fact that there were no hospitals selected to testify at the Panel’s March or August meetings.**

In the proposed rule, CMS notes that there were no requests received from hospitals to evaluate the level of supervision at the March 2013 HOP Panel meeting. CMS then states that it “continues to believe that direct supervision is the most appropriate level of supervision for most hospital outpatient therapeutic services” and that the HOP Panel process “has proved an effective means for the hospital community to identify hospital outpatient therapeutic services that can be safely furnished under general supervision.” The AHA is concerned that CMS may believe that the lack of requests to testify before the March HOP Panel meeting means that the problems that rural hospitals have raised regarding direct supervision have been addressed. **This could not be**

**further from the truth; the issue of direct supervision continues to be a top regulatory concern for CAHs and small, rural PPS hospitals.** Instead, we submit that the absence of requests to testify is a result of several factors: (1) the continued unfamiliarity of hospitals with the role of the HOP Panel and its process; (2) the complex and burdensome process that hospitals must go through to have a presentation accepted by CMS; and (3) the difficulties and expense involved in fielding a team of clinical and administrative staff from these financially and workforce-challenged hospitals to travel to Baltimore for the HOP Panel meeting.

**To address the first factor of hospital unfamiliarity with the HOP Panel process, the AHA continues to recommend that CMS prominently post and communicate information about the HOP Panel with sufficient lead time, especially about upcoming HOP Panel meetings and the related opportunity to testify, and CMS's preliminary decisions regarding HOP Panel recommendations and the related 30-day opportunity for public comment.** We recommend that CMS consider posting these announcements on multiple websites, including its main page under CMS News and the OPPS and HOP Panel pages. Further, CMS should announce these opportunities on its Hospital and Physician Open Door Forum calls and push out listserv announcements as appropriate. The AHA uses various means to communicate information about the HOP Panel to hospitals and state hospital associations, and we will continue to do so. However, wider notification from CMS also would be beneficial.

With regard to the second factor – the challenging process CMS established for submitting a presentation – the events associated with planning for the August HOP Panel meeting are pertinent. As we understand it, at least three hospitals initially showed interest in making a supervision-related presentation to CMS with the intent of presenting at the August HOP Panel meeting. CMS rejected one request because the services identified by the presenter had already been evaluated at a previous HOP Panel meeting, and the HOP Panel rules that require new evidence for re-evaluations were not judged by CMS to have been satisfied by the presenter. This was because CMS determined that the evidence presented did not involve recent changes in technology or practice patterns affecting the procedures safety. The other two presentations were voluntarily withdrawn by the requestors after conversations with CMS staff.

**The AHA is very concerned about the high bar CMS has set for submitting evidence for re-evaluations.** In the CY 2012 OPPS final rule in which CMS established the overall HOP Panel process, it states:

“If there has been a previous consideration and decision on the supervision standard for a service, the requestor should submit new evidence to support a change in policy. *For example*, the public could request another review of a previously reviewed service if new information indicates recent changes in technology or practice patterns that affect a procedure's safety. Such a request must be substantiated with new information *such as* a change in clinical practice patterns due to new techniques or new technology.” (emphasis added)

It is our understanding that CMS staff view the statements prefaced by “for example” and “such as” as absolute requirements. That is, unless the potential presenter has new evidence of recent changes in technology or practice patterns that affect a procedure’s safety, CMS rejects the re-consideration. We disagree. Examples are not the rule, instead they describe the sorts of things that could be acceptable but are not necessarily the only things that should be deemed acceptable. Further, if a hospital requesting HOP Panel consideration of a particular service for the first time happens to provide an incomplete or weak justification for general supervision, we do not believe that this should automatically trigger a much more specific and higher bar for evidence if another hospital subsequently wishes to have the HOP Panel reconsider the same service.

**Therefore, we request that CMS staff allow re-evaluations of services previously considered by the HOP Panel when any kind of relevant new evidence is presented, including new evidence of safe and high quality services being performed under general supervision. For instance, CMS should accept facility-specific evidence that demonstrates the absence of or very rare incidents of adverse outcomes under general supervision.**

With regard to the third factor, i.e., the challenges faced by CAHs and small and rural PPS hospitals in fielding a clinical team to come to Baltimore to testify before the HOP Panel, it is notable that for the first time, CMS decided to hold the March HOP Panel meeting via web conference. Presenters were therefore permitted to make presentations without actually traveling to CMS’s headquarters in Baltimore. **We applaud CMS for making available this alternative approach for conducting the HOP Panel meetings. Given this precedent, the AHA recommends that CMS make it a permanent option to allow CAH and small, rural PPS hospital representatives who wish to make presentations to the HOP Panel to do so remotely via web conference, rather than requiring that they present in person.**

## **REFINEMENT OF THE APC RELATIVE WEIGHT CALCULATION**

In the FY 2009 inpatient PPS final rule, CMS split the medical supplies cost center into two – one for relatively inexpensive medical supplies and another for more expensive implantable medical devices (such as pacemakers). In the CY 2013 OPPS final rule, CMS began to use the distinct CCR for implantable devices to calculate the OPPS relative payment weights. In the CY 2014 proposed rule, CMS proposes to continue to use data from the “Implantable Devices charged to Patients” cost center to create a distinct CCR for use in calculating the OPPS relative weights for CY 2014. **The AHA supports this proposal.** We agree that this approach may help address the issue of charge compression in setting cost-based weights for and contain medical supplies.

In addition, in the FY 2011 inpatient PPS final rule, CMS split the general radiology cost center into three – one for general radiology, one for MRI scans and another for CT scans. In the FY 2014 inpatient PPS final rule, CMS finalized its proposal to begin to calculate the inpatient relative weights using one CCR for general radiology, one for MRI scans and another for CT scans. However, CMS notes that its decision to implement additional CCRs for inpatient

payments does not predict what the agency may finalize for CY 2014 OPPS relative payment weights, stating that it would separately evaluate the impacts of implementing any additional CCRs under the OPPS.

When CMS initially proposed to split the general radiology cost center into three, the AHA requested that the agency further consider the impact of adopting those cost centers before finalizing its decision. We expressed concerns that “adopting these cost centers would implausibly reduce the CCRs for these services – so much so, that, in the outpatient setting, it could result in a CT of the chest being reimbursed at a similar level to a routine chest X-ray.” Our concerns have now proven to be valid. If CMS uses three CCRs (one for each of general radiology, MRI scans and CT scans), the general radiology CCR would be 0.2279, but MRI and CT scan CCRs would be reduced to the implausibly low levels of 0.0959 and 0.0502, respectively. These new CCRs would dramatically lower reimbursement for MRI and CT scans in the outpatient setting, as predicted, resulting in a CT of the abdomen or of the head being reimbursed at a similar level to a routine chest X-ray. This inaccurately reflects the resources used for each of these technologies and is inappropriate.

We believe these CCR reductions are occurring because cost reporting requirements do not ensure hospitals capture cost information for capital-intensive services uniformly and consistently. Specifically, they do not require hospitals to allocate radiology overhead to specific imaging items. Accordingly, much of the overhead belonging to MRI and CT scans remains in the general radiology cost center and is not allocated to the MRI and CT scan cost centers, causing them to be inaccurate.

If this proposal is finalized, we are concerned that the enormous reduction in payment for these advanced imaging services would force some hospital imaging centers to close and would compromise patient access to care in a hospital setting. This impact on access to care would be exacerbated by a related impact on imaging services in the physician office setting. This would occur because the OPPS payments would fall below the rates in the physician fee schedule (PFS), causing further cuts as mandated by the *Deficit Reduction Act* (DRA). Specifically, the DRA mandates that the PFS practice expense payments be paid at the lower of the PFS or OPPS rate. These cuts would not be implemented in a budget-neutral manner in the PFS. We are concerned that additional payment reductions would cause some physicians to stop offering these services as well.

In addition, we note that at its August meeting, the HOP Panel recommended that CMS delay implementing the new MRI and CT scans CCRs for rate-setting purposes until data can be reviewed by the HOP Panel at its Spring 2014 meeting regarding the interactions between these proposals and the cumulative impact of this and other proposals in the rule on hospitals.

**We urge CMS to reconsider the impact of these new radiology CCRs in the outpatient setting and not adopt them for use in rate-setting in CY 2014.** Although a respectable number of hospitals are reporting the new cost centers, we are concerned they are not allocating costs among them uniformly and consistently and that MRI and CT scans would be paid

inaccurately if the detailed cost centers are used. The resulting unintended impact on patient access to advanced imaging services across ambulatory care settings would be severe and should be avoided.

## **SEPARATELY PAID OUTPATIENT DRUGS**

**The AHA continues to support CMS’s proposal to pay for separately payable drugs and biologicals at the “statutory default” rate of average sales price (ASP) plus 6 percent.**

Paying at the rate of ASP plus 6 percent, which is allowed in section 1833(t)(14)(A) of the *Social Security Act*, is administratively simple, improves the stability of drug and biological payments and better covers the costs of drug acquisition and pharmacy overhead costs than the payment rates CMS previously established.

## **COLLECTING DATA ON SERVICES FURNISHED IN OFF-CAMPUS PROVIDER-BASED DEPARTMENTS**

In nearly identical sections in the OPSS and PFS proposed rules, CMS cites recent reports of increasing trends of hospitals acquiring physician practices and integrating those practices as hospital outpatient departments. The agency also notes the Medicare Payment Advisory Commission’s (MedPAC) concerns associated with increasing Medicare program payments and beneficiary cost-sharing that could result from such acquisitions. Consequently, CMS requests comment regarding which of several potential information-gathering methods would best allow the agency to analyze the frequency, type and payment for services furnished in off-campus provider-based hospital departments. The agency is considering:

- Creating a Healthcare Common Procedure Coding System (HCPCS) modifier that would be reported with every code for services furnished in an off-campus provider-based department of a hospital via the Medicare physician and hospital outpatient claim forms;
- Asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report; and
- In the PFS proposed rule, creating a new place of service code for off-campus departments of a provider.

**The AHA is concerned that the potential Medicare-only information collection approaches would create additional administrative burden for hospitals and physicians and would result in inconsistent billing approaches between Medicare and non-Medicare payers. However, we understand CMS’s interest in learning more about this rapidly changing environment. Therefore, if CMS is intent on moving forward to collect such information, the least burdensome approach would be to create a new HCPCS modifier to be reported with services that are furnished in off-campus provider-based departments of the hospital. To ensure that the information collected is meaningful and comparable across**

payment systems, the AHA further recommends that CMS utilize the same approach in the PFS and the OPFS.

It is reasonable for CMS to seek ways to evaluate the trend of hospital acquisition of physician practices. Health care delivery is changing rapidly due to the ACA – hospitals and physicians are responding to programs and incentives for care coordination, readmissions and quality measurement. However, proposals to pay the same for ambulatory care services furnished across the hospital outpatient department and physician office settings are misguided, and we agree with CMS that “hospitals...have overall higher resource requirements than physician offices because hospitals are required to meet the conditions of participation, to maintain standby capacity for emergency situations, and to be available to address a wide variety of complex medical needs in a community.” Therefore, the AHA urges CMS to refrain from using the information it would collect as a means to justify implementing “site-neutral” payment reductions, such as the policies that MedPAC and Congress have been pursuing in the context of federal budget cuts. Instead, CMS should recognize that this trend may reflect efforts by hospitals and health systems to provide and improve more integrated and coordinated care delivery that focuses on appropriate utilization, efficiency and outstanding measureable outcomes.

Further, we understand that, unlike in the OPFS proposed rule, the PFS proposed rule also requests comment on creating a new place of service code for off-campus departments of a hospital as part of the CMS-1500 claim form. We would like to note, with regard to hospital outpatient services and payment under the OPFS, a place of service code at the claim level would not provide CMS with the information it needs. This is because a single claim contains hundreds of lines reflecting services that may have been furnished in both on-campus and off-campus parts of the hospital on the same day for the same beneficiary.

## **CODING AND PAYMENT FOR CRITICAL CARE SERVICES**

CMS proposes to continue its CY 2011-2013 policy to recognize the existing Current Procedural Terminology (CPT) codes for critical care services and establish a payment rate based on historical claims data. It also proposes to continue to implement claims processing edits that conditionally package payment for the ancillary services that are reported on the same date of service as critical care services in order to avoid overpayment.

As we have for the last two years, **the AHA recommends that CMS, in setting the payment rate for packaging ancillary services into the critical care services, establish a methodology that ensures that multiple cost report revenue centers are included in the review.** For example, the critical care services provided in the emergency department (ED) would be reflected in the ED cost report line. However, costs for ancillary services (e.g., chest X-ray, EKG, ventilator management) would be reflected in the revenue centers for the respective departments providing the service, such as radiology, cardiology and respiratory therapy.

## **REMOVAL OF DEVICE-TO-PROCEDURE AND PROCEDURE-TO-DEVICE EDITS AND NUCLEAR MEDICINE PROCEDURE-TO-RADIOLABELED PRODUCT EDITS**

In the CY 2014 OPPTS proposed rule, CMS proposes to no longer implement procedure-to-device edits and device-to-procedure edits for device-dependent APCs. Similarly, CMS proposes to no longer require the nuclear medicine procedure-to-radiolabeled product edits for nuclear medicine APCs. In both cases, CMS states that hospitals would still be expected to adhere to the guidelines of correct coding and append the correct device or radiolabeled product code to the claim when applicable. As CMS notes, the difference is that without the edits, the agency would no longer return claims to hospitals when claims do not include the specific procedure and device code pairings or when the HCPCS codes for radiolabeled products do not appear together on claims with nuclear medicine procedures. CMS believes that the edits are no longer necessary due to the several years of experience hospitals have now had in coding and reporting these claims fully, noting that since the edits were first used, CMS has seen “significant improvement and stabilization in reporting of costs.” For these reasons, the agency states that it does not believe that the burden on hospitals of adhering to the edits and the burden on the Medicare program of maintaining the edits is warranted.

The AHA disagrees; the use of these edits, and even the returning of claims to hospitals when claims are not properly coded, is not overly burdensome to hospitals. Instead, it promotes correct-coding discipline, and, ultimately, ensures that that all relevant costs for device-dependent APCs are appropriately included in the claims that CMS will use for rate-setting. **The AHA recommends that CMS continue to use the device-to-procedure and the procedure-to-device edits as well as the nuclear medicine procedure-to-radiolabeled product edits.**

## **PROTON BEAM THERAPY**

Proton beam therapy is a type of external radiation treatment in which protons are targeted to a specific tissue mass by using a stereotactic planning and delivery system. A focused dose of radiation is delivered to the target area, while the surrounding healthy tissue receives minimal radiation. The CPT book provides the following long descriptions for proton beam therapy:

- Simple proton treatment delivery is to a single treatment area utilizing a single non-tangential/oblique port, with custom blocks with (CPT 77522) or without compensation (CPT 77520).
- Intermediate proton treatment delivery (CPT 77523) is to one or more treatment areas utilizing two or more ports or one or more tangential/oblique ports, with custom blocks and compensators.
- Complex proton treatment delivery (CPT 77525) is to one or more treatment areas utilizing two or more ports per treatment area with matching or patching fields and/or multiple isocenters, with custom blocks and compensators.

In CY 2013, APC 0064 (Level I Proton Beam Radiation Therapy) includes two procedures, CPT codes 77520 and 77522. APC 0067 (Level II Proton Beam Radiation Therapy) also includes two procedures, CPT codes 77523 and 77525.

For CY 2014, CMS proposes to assign all four CPT codes for proton beam therapy to a single APC—APC 0667. CMS proposes to do so in order to avoid a violation of the “two times rule,” which exists in APC 0664 since the geometric mean cost of CPT 77522 is more than double the geometric mean cost of CPT 77520 and the volume and percentage of single claims for CPT 77520 fits within CMS’s two times criteria.

The AHA does not believe CMS should compromise clinical homogeneity simply so the agency can avoid a two times rule violation. In the past, CMS has overlooked two times rule violations when warranted, and often for the sake of maintaining clinical homogeneity. We believe the agency should do the same for proton beam services. Specifically, we do not believe it would be appropriate for CMS to place all of the CPT codes into a single APC when this results in an even greater variation (almost three times) in the geometric mean cost between the lowest cost CPT code and the highest cost CPT code. We acknowledge that according to CMS’s current criteria, this is not technically considered to be a two times rule violation because once all four CPT codes are combined into a single APC, CPT code 77520 no longer constitutes at least 2 percent of the single procedure claims in APC 0667. However, there is a clinical homogeneity violation given the important clinical and resource differences that exist between the simple proton beam therapy services and the intermediate and complex.

The long descriptors for these CPT codes make clear that simple and complex proton beam therapy services are clinically different. A clear difference between a simple and complex treatment is the fact that a simple treatment comprises delivering the radiation treatment to a single treatment area utilizing a single port, while the complex treatment delivers treatment to one or more treatment areas utilizing two or more ports per area with matching or patching fields and/or multiple isocenters. This results in the patient being on the treatment table in the treatment room much longer for complex treatments and also results in more therapist time. This is just one example of the clinical and resource consumption differences that exist. **Therefore, the AHA requests that CMS maintain two separate APCs for proton beam services for CY 2014 by assigning CPT codes 77520 and 77522 to APC 0664 and CPT codes 77523 and 77525 to APC 0667.**

## **FECAL MICROBIOTA TRANSPLANTATION**

Fecal microbiota transplantation (FMT), also known as fecal bacteriotherapy, or human probiotic infusion, is a medical treatment for patients with *Clostridium difficile* (*C. difficile*) enteritis or ulcerative colitis. *C. difficile* infection occurs in patients who have been administered antibiotics for a long period of time. The antibiotics destroy important disease-fighting bacterial flora in the intestine. Fecal transplants are believed to restore the bacteria back to normal, and the patient can recover. The fecal transplant works by repopulating friendly flora in the infected

intestines. The donated feces is screened for disease and then mixed with a saline solution to the consistency of a “milkshake.” FMT can be performed by various routes including nasogastric (NG) tube, nasojejunal tube, upper tract endoscopy (EGD), colonoscopically or by retention enema. However, based on an editorial published in the *Journal of Clinical Gastroenterology* (Volume 45, Number 8, September 2011), colonoscopic FMT is the preferred method for the vast majority of *C. difficile* infection patients, and if carried out early, may prevent development of severe infection.

Effective with the 2013 edition of the CPT manual, the American Medical Association developed the CPT code 44705 (Preparation of fecal microbiota for instillation, including assessment of donor specimen) that includes:

- development of the intestinal instillate for the recipient; and
- evaluation of the donor specimen, including the physician review of results of testing the donor’s specimen for infectious pathogens.

The CPT manual instructions require that the actual instillation or fecal microbiota transplant be coded separately using CPT 44799 for either oro-nasogastric tube or enema. Additional instruction in the CPT manual identifies that all laboratory testing provided for the patient is to be reported separately. Based on this instruction and the intent of the CPT code 44705, this is an add-on or “list separately in addition to the primary procedure,” which would be the instillation procedure, e.g., the oro-nasogastric tube or enema.

By contrast, effective Jan. 1, 2013, CMS created HCPCS code G0455, *Preparation with instillation of fecal microbiota by any method, including assessment of donor recipient*, and assigned it to APC 00340, with a payment of \$49.64. The payment for code G0455 appears only to cover the work related to the preparation of the donor fecal microbiota specimen, which may also include the review of the donor lab results for presence of pathogenic microbes. However, the payment does not appear to recognize the work to prepare the patient for the implantation or the instillation of the donor microbes, or the work performed and supplies consumed during the instillation procedure. The additional cost to perform this portion of the procedure would include the supplies, e.g., nasogastric tubes (approximately \$5 each), enema tubes (approximately \$25 each), other disposables including drapes, gloves, gowns (approximate cost of \$20); the overhead expenses are not considered in these additional costs. In addition, if the microbiota instillation is performed via colonoscopy or EGD, the payment does not recognize the cost of the endoscopic procedure. This is demonstrated by the CPT codes and corresponding APC payments as follows:

- Using EGD as method of instillation: Loss of APC 0141 for EGD with code 43200, *Esophagoscopy, rigid or flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)*, with a payment of \$623.45 (minus Significant Procedure, Multiple Reduction, if performed with other procedures).

- Using colonoscopy as method of instillation: Loss of APC 0143 for colonoscopy with code 45378, *Colonoscopy, flexible, proximal to splenic flexure; diagnostic, with or without collection of specimens) by brushing or washing, with or without colon decompression (separate procedure)*, with a payment of \$691.32 (minus Significant Procedure, Multiple Reduction, if performed with other procedures).

**We recommend that CMS delete code G0455 and replace it with three new G codes:**

- 1. Create a new G code for “*Preparation of fecal microbiota with instillation by oronasogastric tube or enema, including assessment of donor recipient,*” and place it in a more appropriate APC to include the costs of the supplies. We prefer that a new code be created (rather than revise existing code G4055) since the meaning of the code would be significantly different and would confuse any future data analysis if the same code would include different methods of instillation.**
- 2. Create a second new G code for “*Preparation of fecal microbiota with instillation by upper endoscopy, including assessment of donor recipient,*” and place it in APC 0143, Level I Upper GI Procedures.**
- 3. Create a third new G code for “*Preparation of fecal microbiota with instillation by colonoscopy, including assessment of donor recipient,*” and place it in APC 0141, Lower GI Endoscopy.**

## **REQUIREMENTS FOR BILLING “INCIDENT TO” SERVICES**

CMS proposes to require, as a condition of payment, that an individual who provides services and supplies “incident to” a physician’s professional services must meet any applicable state requirements, including licensure, and that services and supplies must be provided in accordance with state law. The agency states that it is proposing this regulation to advance the health and safety of Medicare beneficiaries who receive services and supplies incident to a physician’s services.

It is reasonable for CMS to expect that individuals who provide services and supplies incident to a physician’s services do so in compliance with state law. However, the AHA is concerned about the broad nature of CMS’s proposed regulatory text, which states that “[s]ervices and supplies must be furnished in accordance with applicable State law” and that individuals who provide “incident to” services must meet “any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.” Such a broad requirement would allow CMS to deny Medicare payment for technical violations of state laws that are not targeted at patient health or safety, even when care was appropriately delivered and the quality of care was not affected.

In addition, the proposed language goes further than the existing regulations that CMS cites as examples for comparison in the rule (such as 42 C.F.R. 410.20(b), regarding physicians, and 42 C.F.R. 410.75(b), regarding nurse practitioners). Those regulations require that the relevant provider act within the scope of practice as determined by state law – that is, the regulations focus on whether the state allows the provider to deliver the services in question. This is a more limited requirement than the proposed requirement that those providing “incident to” services do so “in accordance with applicable State law” and must meet “any applicable requirement.” **We ask that CMS limit its proposal to state that those providing services and supplies “incident to” a physician’s services must be licensed, trained or otherwise authorized to deliver those services under state law.** This would satisfy the HHS Office of Inspector General’s concern, cited by CMS in the proposed rule, that only “nonphysicians who have the necessary training, certification, and/or licensure, pursuant to State laws, State regulations, and Medicare regulations” provide “incident to” services and supplies, and would be consistent with existing regulations that require practitioners to be licensed or otherwise qualified in compliance with state law.

## **PARTIAL HOSPITALIZATION PROGRAM (PHP) REQUEST FOR COMMENT**

In the proposed rule, CMS expresses interest in examining the payment structure for PHP services in order to determine whether there are alternative methodologies to pay for these services that would reduce unnecessary care while maintaining or increasing quality of care. The questions CMS poses, as well as the AHA’s general responses, follow.

**Would payment based on an episode of care, or a per diem similar to the inpatient psychiatric facility PPS, result in more appropriate payment for PHP services than the current payment structure?** In the absence of any relevant payment research or substantive proposals, we cannot comment on whether an episode of care or a per diem basis for the PHP would result in more suitable payment rates.

The AHA supports CMS’s stated goals to ensure the long-term stability of PHPs and to improve payment accuracy for PHP services. In recent years, the AHA, together with the National Association of Psychiatric Health Systems (NAPHS), has advocated for improvements in the PHP payment structure. This includes revising the PHP to create two levels of PHP payment and using hospital-based cost data to determine hospital-based rates and community mental health center (CMHC) cost data to determine CMHC rates. However, despite these improvements, the payment rates for the PHP APCs continue to fluctuate significantly from year to year, making budgeting difficult for hospital-based PHPs. For instance, the rate for APC 0175, Level I PHP, is proposed to increase 14 percent while the rate for APC 0176, Level II PHP, is proposed to fall by 8 percent from 2013 to 2014. Similarly, 2013 payment rates for hospital-based PHP services increased 12.5 percent and 19.4 percent for Level I and Level II PHP services, compared to 2012 rates.

We believe it would be useful to evaluate the way in which the overall Medicare behavioral health benefit is structured. Compared to the scope of services many private health insurers cover, the Medicare benefit is far narrower. For instance, Medicare beneficiaries are currently limited to just 190 days of inpatient psychiatric hospital care in their lifetime. No other Medicare inpatient hospital service has this type of arbitrary cap on benefits. In addition, rather than covering the full continuum of behavioral health care services, Medicare currently covers only inpatient psychiatric care, hospital-based and CMHC-based PHP services and office-based services. Further, the PHP benefit is drawn very narrowly so as to cover care only for the most acutely ill patients who would otherwise require hospitalization. The parts of the continuum missing from the current Medicare benefit include formal coverage of intensive outpatient care, residential treatment, psychosocial rehabilitation and care management. This makes it difficult for providers to provide Medicare beneficiaries with the appropriate services at the right level and time.

We understand that broadening the Medicare behavioral health benefit structure to encompass the other components of the continuum would require statutory changes. Making smaller changes, such as revising the PHP payment structure, will not address the larger limitations of the Medicare benefit design. Therefore, we were pleased to see the recent open letter to the behavioral health community from Senate Finance Committee Chairman Max Baucus (D-MT) and Ranking Member Orrin Hatch (R-UT) requesting input on how to improve the nation's behavioral health system, as well as the president's call for a national conversation on behavioral health. The AHA has been engaged in this national dialogue and will submit formal comments to the Senate Finance Committee in response to the committee's request.

**Does the current physician recertification requirement, which requires the first recertification as of the 18<sup>th</sup> day of PHP service, reflect current PHP treatment practices or should the regulation be changed to another standard that accords with best practices?**

The AHA does not believe that there is any reason to change the 18-day recertification and the "no longer than 30 days" length of time for a subsequent recertification. Our member hospitals have not identified this as a problem, and we are not aware of any best practices that would suggest the need for such a change.

**What requirements should be included in the written plan of treatment to better direct PHP resources toward appropriate discharge and follow-up with appropriate support services?**

Of the suggested additions to the written plan of treatment, the AHA supports including a full list of patients' medications, dosages, and any necessary prescriptions as well as the next scheduled appointment with a psychiatrist or qualified practitioner who may bill for his or her professional services under Medicare Part B, including the phone number, address and appointment date and time. However, we do not believe that it would be feasible for a PHP to be able to provide a "confirmed place to live in a stable environment with support services" for its patients. Among the admission criteria for PHP is a requirement that the patient "have an adequate support system to sustain/maintain themselves outside the partial hospitalization program." While a PHP program may be able to provide some limited help for a patient to

maintain and enhance this stable environment, the program cannot ensure it nor keep a patient in PHP until it can be established.

**If CMS were to establish quality measures for PHP services and require quality data reporting, what should be included in those measures? In addition, should those measures be similar or identical to those measures established in the inpatient psychiatric facility quality reporting program?**

The AHA supports measuring the quality and safety of behavioral health care across the continuum and believes it may be appropriate to implement measures for PHPs. **However, any measures selected to assess PHPs should be specified, tested and National Quality Forum (NQF)-endorsed for that care setting and reviewed by the Measure Applications Partnership (MAP) before they are proposed for the program.** One potential source of measures to assess PHPs is the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program. With appropriate modification, the use of some IPFQR measures for PHPs could promote enhanced care coordination between PHPs and inpatient psychiatric facilities (IPFs). In particular, CMS should consider modifying two pairs of IPFQR measures for use in assessing PHPs – Hospital-Based Inpatient Psychiatric Services (HBIPS) 4 and 5 (multiple antipsychotics) and HBIPS 6 and 7 (continuity of care).

HBIPS 4 requires the identification of patients who are discharged on two or more antipsychotic medications, while HBIPS 5 reports the number of patients discharged on multiple antipsychotic medications with appropriate justification. Antipsychotics are important tools in managing behavior, but often have significant side effects, especially when multiple antipsychotic medications are used concurrently. It is often appropriate to reduce (or “taper”) the number of antipsychotics given to patients, but the tapering of drugs cannot always be completed during an inpatient hospitalization. It would be appropriate to measure PHPs on HBIPS 4 and 5 because antipsychotic medication tapering can and often does continue in PHPs. Using setting-appropriate versions of HBIPS 4 and 5 in both IPFs and PHPs might encourage better coordination of the use of antipsychotic medications across these two settings.

Similarly, HBIPS 6 measures whether a post-discharge continuing care plan is created, while HBIPS 7 measures whether the post-discharge continuing care plan is transmitted to the next level of care provider. A plan of care provides the next provider with a summary of a patient’s course of treatment, discharge medications and any recommendations for ongoing care. Whenever a patient changes care setting, the transmission of a plan of care equips the entire health care team with important information to shape a patient’s treatment plan. Assessing both IPFs and PHPs on these measures could reinforce the need for ongoing, two-way communication across a patient’s behavioral health care team.

## **OUTPATIENT QUALITY REPORTING (OQR) PROGRAM**

The *Tax Relief and Health Care Act of 2006* required CMS to establish a program under which hospitals must report data on the quality of outpatient care in order to receive the full annual

update to the OPPS payment rate. Hospitals failing to report the data will incur a reduction in their annual payment update factor of 2 percentage points.

**Proposed Measure Removal for CY 2016. The AHA supports the removal of OP-19 and OP-24 from the OQR program, and commends CMS for its responsiveness to stakeholder concerns about these two measures.** OP-19 assesses whether a patient or patient’s caregiver receives a “transition record” containing certain data elements (e.g., discharge diagnosis, medications, test results) upon discharge from the ED. Because the measure specifies that a patient’s transition record may be given to a caregiver, hospitals raised concerns that sensitive information might be disclosed against a patient’s wishes. OP-24 assesses the proportion of outpatients undergoing certain cardiac procedures (e.g., valve surgery) who are referred to cardiac rehabilitation. We agree this should be removed given it is difficult to determine the purpose of a given outpatient visit using only claims data and to identify specific visits resulting in a referral to rehabilitation care.

**However, we continue to urge CMS to remove several other measures from the OQR program, based on recommendations from the MAP.** The MAP is a multi-stakeholder board charged with making annual recommendations to the HHS Secretary regarding which measures should be included in national quality reporting programs. In early 2012, the MAP conducted a review of measures from CMS, including measures in the current OQR program. The MAP suggested that the seven previously finalized OQR measures listed below were directionally right, but not appropriate for use in the OQR program as currently constructed.

<b>OQR Measures Not Recommended by the MAP</b>
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-14: Simultaneous Use of Brain CT and Sinus CT
OP-15: Use of Brain CT in the Emergency Department for Atraumatic Headache
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP-22: ED Patient Left Without Being Seen
OP-25: Safe Surgery Checklist Use

The AHA has commented to CMS on several occasions that the imaging efficiency measures (OP-9, OP-10, OP-14 and OP-15) should not be included in the OQR program because several of them have failed the NQF-endorsement process. Further, we continue to hear from members that the implementation of OP-20, OP-22 and OP-25 has been difficult and produced results that are not accurate or suitable for public reporting. Finally, this year’s MAP assessment recommended the removal of OP-22 because the measure has lost NQF endorsement. **Given this assessment and the MAP recommendations, the AHA urges CMS to immediately remove these seven measures (see chart above) from the OQR program.**

**Proposed New Measures for CY 2016.** CMS proposes to add five new measures to the OQR program for the CY 2016 payment determination. All five measures would be collected and

reported by hospitals beginning in CY 2014. Each measure is endorsed by the NQF and was reviewed by the MAP. We address each of CMS's proposals below.

*Influenza Vaccination Coverage Among Healthcare Personnel (OP-27).* CMS proposes to add to the OQR program the same Influenza Vaccination Coverage Among Healthcare Personnel measure that is currently reported in other federal programs, including the inpatient quality reporting (IQR) program for acute care hospitals. The measure is endorsed by the NQF, and was supported for inclusion in the OQR program by the MAP. CMS proposes to collect this measure using the Centers for Disease Control and Prevention's (CDC) National Health Safety Network (NHSN), the same mechanism used in other programs to collect the measure.

**The AHA supports the addition of the influenza vaccination measure to the OQR program. However, given that acute care hospitals also report this measure, CMS should clarify how the location of outpatient areas relative to acute care hospitals and sharing of staff between inpatient and outpatient areas affect measure reporting.** The location of outpatient areas relative to the hospital can be challenging to define. The outpatient areas for some hospitals are "on-site," or located inside the same building as the acute care facility. Other outpatient areas may be "on campus" – that is, located in very close proximity to the hospital (e.g.—across the street), but not physically attached to it. Other outpatient areas are "satellites" located a significant distance from the hospital. The acute care hospital may share its staff and infection control policies with on-site, on campus, or satellite locations.

The existing FAQ guidance on the NHSN website suggests that "acute care facilities should count [healthcare personnel] working in all units that are physically considered a part of the inpatient acute care facility site, regardless of the size or type of unit." The FAQ also notes that if the specific unit is "staffed by acute care facility workers, follows the acute care infection control policies, and answers to the acute care administration, then the workers in that location should be included for the acute care influenza vaccination coverage."<sup>1</sup> Many of our member hospitals have on-site and on-campus outpatient areas that share management, infection control policies and personnel with the acute care facility. They have, therefore, counted on-site and on campus locations in the reporting of healthcare flu vaccination status for the hospital IQR program.

We believe that the intention of the healthcare personnel influenza measure is to encourage personnel in a patient care facility managed by a common entity – and any patient care areas located within that facility – to receive flu vaccination. **Therefore, CMS should allow hospitals with only onsite and on campus outpatient areas to attest that their healthcare personnel flu vaccination reporting is completed through the acute care hospital's quality reporting program, thereby receiving credit for reporting in both the IQR and OQR programs.** Given that the proposed data reporting periods and submission deadlines for the measure are the same as those for other federal quality programs, we believe attestation would promote alignment across programs, and avoid unnecessary burden. However, if a hospital has satellite outpatient areas, it would be appropriate for the hospital to collect and submit data for those areas.

*Cataract Surgery Outcome and Colonoscopy Follow Up Measures.* CMS proposes to add four measures that have previously been used in the Physician Quality Reporting System (PQRS) to the OQR program. The agency proposes these measures due to the high volumes of both cataract surgeries and colonoscopies performed nationally, and would collect aggregate performance data on the measures using a web-based tool. The specific measures are briefly summarized below:

- *OP-28: Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures.* OP-28 assesses the percentage of patients who have undergone cataract surgery who subsequently experience complications such as retained nuclear fragments, wound dehiscence or retinal detachment.
- *OP-31: Cataracts; Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery.* OP-31 measures the percentage of cataract surgery patients whose visual function has improved within 90 days of surgery.
- *OP-29: Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients.* OP-29 measures the percentage of patients aged 50 years and older at normal risk for colon cancer whose medical records include a recommendation that a repeat colonoscopy should be performed in 10 or more years.
- *OP-30: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps; Avoidance of Inappropriate Use.* OP-30 is intended to measure the repeat colonoscopy intervals for patients at higher risk of colon cancer (i.e., patients with a prior history of colonic polyp). The measure assesses the percentage of colonoscopy patients with a prior history of colonic polyp who have an interval of three or more years since their last colonoscopy.

The AHA agrees that patients may benefit from information about the outcomes of cataract surgeries at outpatient facilities so that they can make fully informed decisions about their care. Similarly, colonoscopies are important diagnostic procedures that can identify colon cancer early in its progression; nevertheless, they should not be used more than necessary. It also is reasonable for CMS to look to other quality reporting programs, such as PQRS, to see if any measures can be re-purposed for the OQR. However, the purpose of the OQR program is to provide the public with information about the quality of care provided by outpatient facilities. As such, all stakeholders must have confidence that the selected measures will accurately portray facility level performance, and that hospitals can accurately collect it without undue burden.

**Unfortunately, while all four measures are NQF-endorsed, they have not yet been specified or tested at the facility level, providing little confidence that they will generate accurate facility-level performance results. Furthermore, the AHA is very concerned that the measures as specified are not feasible to collect for the purposes of the OQR program. For these reasons, we urge CMS not to adopt these measures for the OQR at this time.**

In its review of potential OQR measures earlier this year, the MAP voted to support OP-28 and OP-31, and support the direction of OP-29 and OP-30. The MAP's recommendation for each of the four measures includes the following caveat: "measure should be tested and NQF-endorsed for the facility level of analysis."<sup>ii</sup> Specifying and testing measures at the intended level of measurement provides assurance that the measure results accurately reflect the performance of the entity being measured. For instance, facility-level measure testing data would give CMS and hospitals an indication of what minimum number of cases is needed for the measure to reflect real performance, and not just random variations in patient populations. This is especially important when measure results are publicly reported and compared to those of other facilities. Facilities also use measure specifications to structure data collection strategies. Specifications will often include approaches to collecting a sample of data that help mitigate the burden of data collection.

In the proposed rule, CMS does not indicate whether it has undertaken new testing of the measures. However, a review of the NQF website indicates that OP-29 and OP-30 are currently being reviewed by the Gastrointestinal/Genitourinary Steering Committee for re-endorsement by the NQF. Unfortunately, the level of testing performed on each measure is explicitly noted as the "individual clinician," and not the facility level.<sup>iii</sup> The updated measure specifications also include new electronic measure specifications. However, there is no indication that the electronic specifications have been tested at the facility level.

**We further note that three of the four measures – OP-29, OP-30 and OP-31 – rely on the use of CPT category II codes.** These codes can be used on claims submitted for payment under the PFS. However, they are not used for the OPDS, and most hospitals do not collect them. Therefore, most hospitals would be unable to use claims data to abstract the measures for the OQR program, thereby eliminating a data collection mode that could substantially mitigate the burden of data collection.

**If CMS wishes to implement these measures in the future, we urge it to re-specify and re-test them to ensure that they can be collected by hospitals and generate reliable and valid results. Once it has completed these steps, the agency should submit the updated measures for NQF endorsement, and have them re-reviewed by the MAP.** These steps will ensure that any resources dedicated to collect the measure will result in trustworthy information that the public can use to inform its health care choices.

**Data Reporting.** CMS proposes to continue the general data submission timeframes for the measures finalized in previous rules. CMS also proposes data reporting modes and timeframes for the five new measures in the program. Hospitals would be expected to submit aggregate data for four of the five new measures, cataract surgery (OP-28 and OP-31) and endoscopy (OP-29 and OP-30), using the same web-based tool used for OP-22. The healthcare provider influenza vaccination measure would be submitted using the CDC's NHSN, the same mechanism used for healthcare-associated infection (HAI) measures in other federal quality reporting programs. **The AHA supports these proposals, but notes that OP-28, OP-29, OP-30 and OP-31 must be re-specified, tested and NQF endorsed at the facility level of analysis before they are added to**

**the OQR program. As noted above, we also urge CMS to clarify how the location of outpatient areas relative to acute care hospitals, as well as sharing of staff between inpatient and outpatient areas, affects influenza vaccination measure collection.**

**Extraordinary Circumstances Extension or Waiver.** CMS previously finalized a process to grant hospitals OQR data submission extensions or waivers due to extraordinary circumstances such as natural disasters. CMS proposes only one minor change to the existing process. Specifically, the agency proposes that it may grant extensions or waivers to hospitals if it determines that a systemic problem with a CMS data collection system directly or indirectly affects the ability of hospitals to submit data. **The AHA greatly appreciates and supports this proposal.**

## **HOSPITAL VALUE-BASED PURCHASING (VBP)**

Most programmatic changes to the hospital VBP program were explained in the FY 2014 inpatient PPS proposed rule. However, CMS proposes two additional changes in this rule.

**Baseline and Performance Periods for HAI Measures.** CMS proposed three HAI measures for the FY 2016 VBP program in the inpatient PPS proposed rule: central line-associated blood stream infection (CLABSI); catheter-associated urinary tract infection (CAUTI) and surgical site infection (SSI). However, the agency inadvertently omitted proposals for the baseline and performance periods for all three measures in the inpatient PPS rule. Thus, it proposes a baseline period of CY 2012 (Jan. 1, 2012 – Dec. 31, 2012) and a performance period of CY 2014 (Jan. 1, 2014 – Dec. 31, 2014).

**While the AHA believes these performance periods are appropriate for the purposes of the VBP program, we continue to urge CMS to remove the CAUTI and CLABSI measures from the VBP program to eliminate overlap with the Hospital-Acquired Condition (HAC) penalty program. The HAC and the VBP programs use disparate ways to identify good versus bad performance. Including the same measure in both programs may send conflicting signals to hospitals and patients regarding the true state of performance on these measures.**

As currently constructed, it is entirely possible that performance in one program could appear acceptable or even good, but may lead to a payment penalty in the other program. Each program uses different measure performance periods, causing differences in measure performance. Indeed, the HAC program performance period uses two years of data, while the VBP program uses only one. Moreover, the scoring methodologies of the two programs are vastly different, which could lead to hospitals having disparate scores for the same measure, as well as disparate payment incentives. In the VBP program, a portion of hospital reimbursement is withheld, with hospitals having an opportunity to earn incentive payments back based either on how well the hospitals perform on certain quality measures or how much the hospitals' performance improves

from a baseline period. The HAC Reduction Program, by contrast, assesses penalties based on scoring in the top quartile of HAC measures.

**Independent CMS Review Process.** The VBP program includes a review and corrections process for hospitals to preview their VBP performance score and submit an appeal to CMS if they believe it is incorrect. In the rule, CMS proposes to make an additional “independent CMS review” process available to hospitals. Hospitals can request this independent review only after completing the review and corrections process. The agency intends to complete independent reviews within 90 days of the date of request. **The AHA supports this proposal.**

## **AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM**

The ACA required CMS to establish a program under which ASCs must report data on the quality of care delivered in order to receive the full annual update to the ASC payment rate. ASCs failing to report the data will incur a reduction in their annual payment update factor of 2 percentage points beginning with the CY 2014 update.

**CY 2016 Proposed Measures.** CMS proposes to add four of the same measures to the ASCQR for CY 2016 as it proposed to add to the OQR program:

- Complications within 30 days Following Cataract Surgery Requiring Additional Surgical Procedures
- Cataracts – Improvement in Patients Visual Function within 90 Days Following Cataract Surgery
- Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

The agency notes that it wishes to add the same measures to both the ASCQR and OQR programs because it believes hospital outpatient departments and ASCs provide similar surgical and related non-surgical services. **However, given that these measures have not been tested at the ASC level, we do not support their addition to the ASCQR program.** We refer the agency to our discussion of the lack of specifications, testing and NQF endorsement discussed in the OQR section of this comment letter. It is crucial that measures be specified, tested and NQF-endorsed at the intended level of measurement to ensure that measure results are credible, and so facilities can feasibly collect the data.

**If CMS wishes to implement the measures in future ASCQR programs, we urge it to re-specify and re-test the measures to ensure that they can be collected by ASCs, and generate reliable and valid results. Once it has completed these steps, the agency should submit the updated measures for NQF endorsement, and have them re-reviewed by the MAP.**

Lastly, we note that these measures as currently constructed may not provide the most meaningful assessment of ASC care. Indeed, while ASCs are the site of outpatient surgical procedures, follow-up care may not be provided at that same ASC. This makes tracking colonoscopy follow up intervals considerably more challenging for ASCs. CMS would need to carefully examine any ASC-level measure testing results to determine if the measures overcome this limitation.

**Data Reporting.** CMS proposes minor modifications to the data submission timeframes for the measures finalized in previous rules, and proposes a minimum Medicare patient volume to be eligible for the program for CY 2016. CMS also proposes the data reporting modes and timeframes for the four new measures in the program.

*Minimum Medicare Volume.* CMS collects and calculates some ASCQR program measures using Quality Data Codes (QDCs) reported by ASCs on Medicare Part B claims. However, CMS also has determined that some ASCs have a relatively low volume of Medicare claims, making it difficult to calculate claims-based measures. Thus, beginning with the CY 2016 payment determination, CMS proposes that ASCs must have a minimum of 240 Medicare claims (primary plus secondary payer) during a reporting period to be eligible for the ASCQR program. ASCs falling below this threshold would not be eligible for the program.

**While the AHA supports this proposal, we remain concerned about the use of QDCs to collect ASCQR measures. While we appreciate that using a claims-based reporting mechanism can lessen the burden of data collection, the measures using the QDC reporting mechanism were not specified, tested or NQF-endorsed for claims-based reporting.** Indeed, a search of the NQF website reveals that the NQF-endorsed data source for the measures is “paper medical record.”<sup>iv</sup> From an operational standpoint, it can be challenging for facilities to ensure that QDCs are included on claims in the first place. Moreover, because the results derived from the QDC reporting mechanism have not been validated against the results from chart abstraction, we are concerned that the data being collected using QDCs do not accurately reflect ASC performance.

**We urge CMS to work with the developers of these measures to develop, test and obtain NQF endorsement for a claims-based data collection process.** This will ensure that the QDC reporting mechanism yields accurate, reliable results suitable for public reporting purposes.

*Structural Measure Data Submission.* CMS proposes to continue to require ASCs to report ASC-6 (Safe Surgery Checklist Use) and ASC-7 (ASC Facility Volume Data on Selected ASC Surgical Procedures) using a web-based reporting tool on QualityNet. The data reporting period would remain the calendar year two years prior to payment determination. Thus, for CY 2016, ASCs would report on the period from January 1, 2014 through December 31, 2014. However, the agency proposes to expand the submission timeframe to July 1 through August 15 of the year prior to payment determination. This submission timeframe would align with that of the four newly proposed measures. **The AHA believes this is an appropriate change, but also**

**continues to urge CMS to remove the structural measures from the ASCQR program because neither measure is NQF-endorsed.**

*Data Submission for Newly Proposed Measures.* CMS proposes that the four new measures proposed for CY 2016 would be reported using a web-based tool on QualityNet. ASCs would be expected to collect aggregate data for a time period two years prior to payment determination, and submit the data between Jan. 1 and Aug. 15 of the year before payment determination. Thus, for CY 2016, the data would be collected for encounters from Jan. 1 through Dec. 31, 2014, and reported on QualityNet between Jan. 1 and Aug. 1, 2015. **The AHA does not support this proposal because we do not support the addition of the four new ASCQR measures at this time. CMS must re-specify, test and obtain NQF endorsement of the measures at the facility level of analysis before they are added to the ASCQR program.**

## **CHANGES TO THE QUALITY IMPROVEMENT ORGANIZATION (QIO) REGULATIONS**

CMS proposes to make substantial revisions to the existing regulations for the QIO program based on statutory changes included in the *Trade Adjustment Assistance Extension Act of 2011*. These statutory changes provided CMS with added flexibility in how it administers the QIO contracting process. Under the proposed rule, CMS would establish a regulatory framework that incorporates this flexibility, so that it could:

1. alter the geographic areas covered by QIO contracts and focus on the goals of a particular QIO contract rather than emphasizing a state-by-state geographic framework;
2. expand what types of organizations could have QIO contracts, which would include health care facility associations; and
3. divide up the functions of QIOs among different organizations serving the same QIO area. Under this approach, CMS could separate two of the main functions of QIOs – the beneficiary case review functions and the quality improvement initiatives – and assign these two functions to different organizations for the same area.

We commend CMS for using its increased flexibility to contemplate alternative structures for the QIO program. Many different models exist for enhancing quality, including the Hospital Engagement Network (HEN) improvement model, a major HHS initiative that has achieved notable success in improving patient safety and quality of care across the U.S. The largest HEN contract is held by the Health Research & Educational Trust (HRET), the research arm of the AHA. Interim data suggest that HRET, working in collaboration with 31 state hospital associations over the past 18 months, has so far helped hospitals lower readmissions by 23 percent, CLABSIs by 49 percent, early elective deliveries by 23 percent, obstetrical adverse events by 27 percent, and surgical infections by 27 percent, in addition to other progress. Although the future of the HEN project is unclear, we believe that the proposed changes in the QIO provisions could allow the entities involved to bring these successful strategies to the QIO program, benefitting patients, hospitals and the Medicare program.

While statutory changes will allow health care facility associations to have QIO contracts, some associations that have demonstrated an ability to improve quality of care might still be prevented from serving as a QIO under the proposed definition of a health care facility affiliate. The proposed regulatory language at § 475.105(a)(2) precludes health care facility affiliates from eligibility for a QIO contract and defines health care facility affiliate as “an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility in the QIO area.”

We believe it makes sense that health care facility affiliates should not conduct *case reviews* of health care facilities in the QIO area. However, we believe health care facility affiliates could be excellent organizations to lead the *quality improvement functions* of QIOs, as evidenced through the achievements made through the HEN initiative. For example, state hospital associations have developed trust and collaborative partnerships with their members, and we think hospitals would be more inclined to join quality improvement initiatives with organizations they trust. **We urge CMS to change the language in the final rule so that health care associations, such as state and national hospital associations whose boards may be comprised largely of officers or trustees of hospitals, would be eligible for QIO contracts that focus on quality improvement efforts.** Otherwise, CMS would preclude some of the entities with whom it currently partners under the HEN program from becoming QIO contractors.

Further, while we agree that it would be very helpful to separate the case review functions from the quality review functions, some have read the proposed rule to suggest that CMS might separate the case review functions into even smaller bundles, with the idea that hospitals would work with more than one QIO for different types of reviews. For example, we would hope that CMS would not separate the beneficiary complaint reviews from the general quality of care reviews. We believe such an approach is inconsistent with CMS’s intent as well as current regulations, and we are concerned that multiple arrangements would be confusing, challenging to manage and expensive to maintain. **We urge CMS to consider that requiring multiple contracts for case reviews could be burdensome and should be avoided.**

The same concern exists for quality improvement initiatives. One could read the proposed rule to allow the quality improvement functions of QIOs, as well as the support QIOs provide for quality measurement programs, to be divided and delegated to separate organizations. For example, one QIO could focus on assisting with cardiac care improvements, another on cancer care projects, another on changes in pediatric care, and so forth. **Hospitals should be able to work with one or two QIOs that offer quality improvement opportunities and quality measure program assistance, with access to QIOs that are subject matter experts on various functions such as measurement reporting.**

We believe most hospitals and health systems would want to focus their efforts by partnering with one or two QIOs for quality improvement activities and would expect that QIO to bring assistance in data collection and reporting, quality improvement techniques and access to expert advice and information related to the specific improvement project(s) being undertaken. If

hospitals, particularly small or resource-strapped hospitals, had to manage many agreements to engage in quality improvement efforts, we are concerned that it would force them to limit their involvement in quality improvement activities. To date, CMS has handled this complexity by allowing hospitals to work with a single QIO for multiple improvement projects, just like many patients choose to work with a single primary care clinician. However, those primary care clinicians need ready access to specialists when the patient's problem is complex or requires specific expertise. Similarly, special expertise is needed from time to time in the QIO quality improvement framework.

We also think that CMS is correct in acknowledging that greater standardization and nationally-recognized expertise is useful for a specific activity that our member hospitals especially depend on: assistance with education and data submission for quality measurement programs and technical advice related to quality measurement specifications. For example, the agency chose to create National Coordinating Centers (formerly QIO Support Contractors or QIOSCs) to support the IQR, OQR and other functions. We agree that this responsibility of the QIOs needs consistency and standardization across states and regions, and we think that the coordinating centers complement the direct assistance provided by a hospital's current regional or state QIO. **We hope that CMS will continue to use a standardized approach for this activity, supported by individual QIOs that offer knowledgeable, trusted relationships and on-site direct assistance to hospitals.**

In the proposed rule, CMS outlines criteria it would consider when evaluating an organization's ability to conduct quality improvement initiatives and case reviews. For example, CMS would examine the organization's proposed processes, capabilities, and methodologies, as well as the proposed involvement of physicians and other practitioners in the QIO area with relevant expertise, among other factors. CMS should consider the following additional criteria when awarding QIO contracts that involve quality improvement initiatives:

**1. The success of coordinated quality improvement initiatives depends in large part on trust, and organizations that are awarded a QIO contract for quality improvement tasks should demonstrate the ability to foster a relationship of trust with providers, including clinicians and the executive leadership of provider organizations.** For example, some hospitals have developed strong working relationships with their QIOs and prefer to continue to work with them on quality improvement because of the trust already established. Other hospitals, such as those involved in the HEN program, have become very effective partners with their state hospital associations and would welcome the ability to draw upon that foundation and the HEN infrastructure to continue to improve and enhance patient care. The ability of a QIO to foster trust is especially important if CMS implements a regional approach to the quality improvement functions. CMS would need to consider and require bidders for QIO contracts to propose the methods by which a QIO, especially those headquartered in a different geographic area than providers, would achieve a collaborative partnership and secure needed input. CMS could also consider letters of recommendation from partnering organizations that attest to a bidder's ability to create trust.

**2. Organizations seeking QIO contracts for quality improvement initiatives should be able to foster relationships among stakeholders.** Establishing a coordinated care delivery system requires many types of providers to work together. For example, to effectively reduce readmissions, hospitals have reached out to community providers such as nursing homes and home health organizations in a way that creates a continuum of care for patients. QIOs should demonstrate the ability to support providers as they break down the silos in the health care delivery system and build a more coordinated infrastructure.

**3. QIO quality improvement initiatives should complement, and not duplicate, quality improvement efforts already under way through statewide, regional or federal efforts.** Coordinated quality improvement projects have blossomed over the past few years, with multiple quality initiatives organized by CMS, the Agency for Healthcare Research and Quality, state governments, state hospital associations, patient safety organizations, QIOs and others. CMS should ensure that hospitals taking part in a coordinated initiative, such as a hospital working to reduce early elective deliveries through a statewide project, would not be asked to replicate its efforts through a similar QIO quality initiative. QIOs should be permitted flexibility to offer different types of assistance to providers in recognition of the many different approaches that may actively be pursued by providers in a given jurisdiction.

**4. QIOs working on quality improvement initiatives should demonstrate the ability to collect meaningful data, analyze that data and use it to improve care.** Although many areas of care can be measured, not all measurement leads to quality improvement and information should not be submitted solely for the purpose of data collection. Hospitals must be able to use the data collected to improve care.

In addition, we support the idea of using a regional approach to conduct case reviews. **However, we believe that CMS's evaluation of organizations to perform the case review functions should also include an analysis of whether the organization can conduct reviews in a fair and neutral manner.** It is vitally important for complaint investigators to act objectively and to foster and value communication with providers as they resolve complaints. An organization conducting reviews also should have mechanisms in place to ensure that it comprehends and considers regional characteristics. Additionally, CMS should clarify that reviews of practitioners should generally be conducted by the same type of practitioner. For example, only licensed doctors of medicine or osteopathy should review other doctors of medicine or osteopathy.

We also support the extension of the QIO contract period to five years.

## **TREATMENT OF CAH METHOD 2 PHYSICIANS UNDER THE EHR INCENTIVE PROGRAM**

**The AHA appreciates the agency's proposal to allow physicians who provide services in the outpatient departments of CAHs and have their services billed by the CAH under Method**

**2 to participate in the EHR incentive program in 2013.** It is unfortunate that CMS's information systems have, until now, unfairly prevented these physicians from participating in the EHR Incentive Program because they could not use data from the UB-04 claims to identify services provided by the physician. Nevertheless, we urge CMS to adopt both its proposed approach to identifying eligible physicians using 2013 claims data submitted on the UB-04 and its proposed hold harmless policy for those physicians who are determined to be eligible using the 2012 data, but not the new 2013 data. **We also urge CMS to act as quickly as possible to provide detailed guidance on how physicians can take advantage of this policy change, and stand ready to assist the agency in educating rural providers about it.**

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<sup>i</sup> This frequently asked question can be found at the following link: <http://www.cdc.gov/nhsn/faqs/FAQ-Influenza-Vaccination-Summary-Reporting.html#Quest9jan13>

<sup>ii</sup> See National Quality Forum, *MAP Pre-Rulemaking Report: 2013 Recommendations on Measures under Consideration by HHS*, pp. 164-165. The report can be accessed at <http://www.qualityforum.org/map>

<sup>iii</sup> For OP-29 specifications, see <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72857>. The reference to level of testing can be found on page 27. For OP-30, see <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72858>. The reference to level of testing can be found on page 26.

<sup>iv</sup> See the NQF's Quality Positioning System (QPS) at <http://www.qualityforum.org/QPS>

## **AHA Members' Responses to CMS's Request for Comment on the Impact of Ending the Enforcement Moratorium Involving Direct Supervision of Outpatient Therapeutic Services**

The AHA solicited responses from critical access hospitals (CAHs) and small, rural prospective payment system hospitals on CMS's request for public comment regarding:

- the potential impacts on access to care and quality of care for specific services that may result from allowing the enforcement moratorium to end; and
- the specific services for which CAHs and small, rural hospitals anticipate difficulty complying with the direct supervision policy, including specific factors that may contribute to the lack of available staff.

Their comments are provided below. The names and specific locations of the 11 responding hospitals are removed to protect their confidentiality.

### CAH in Kansas

XX Health Center, a CAH located in Kansas, manages the care of many who require outpatient therapeutic services. Many of our patients are elderly and are both physically and financially unable to travel to other healthcare facilities. Additionally, they prefer to be in a facility where they know the nursing staff and feel comfortable with the care and the manner in which it is provided.

Our facility operates without medical staff in the facility 24 hours per day. We do not employ physicians; we contract with our local physician practice to cover ER and visit our patients daily around their clinic schedules. We have a long-standing relationship with the physicians in the community, and they are readily available and willing to be at the hospital as needed in an emergent situation. However, the physicians are not available throughout the day and night to supervise all of the outpatient therapeutic services that this facility provides to patients. This is an impractical and unnecessary approach to delivering healthcare in rural America.

The procedures that take place in our facility have been successfully practiced under general supervision without any adverse results. Our nursing staff is trained to start IV's and administer IV antibiotics, and they have done so forever with positive patient outcomes. We have had zero anaphylactic reactions to antibiotic regimens as our nursing staff is properly trained and has general oversight from local physicians. Furthermore, the facility has the necessary protocols in place to handle emergent conditions in the event that they occur. Our community, like other rural communities around us, has been successful at providing quality care with positive patient outcomes without direct physician supervision.

Enforcing direct supervision on the outpatient services that our hospital handles every day will create more risk for the patient than currently exists today with general oversight. That patient will now have to travel, if they are able, to have the outpatient service, and it is likely that they may elect to discontinue the outpatient care because of cost or inability to travel. Additionally, the direct supervision requirement will be very difficult to implement because of the shortage of

physicians in our area, and CMS's policy, if implemented, will severely limit the types of services that rural hospitals can offer to their communities.

Rural hospitals are key to the survival of small towns throughout the state. Without successful hospitals in the community, the survival of the small town population is at risk. Efforts need to be made to enhance and help rural hospitals instead of stripping away their ability to offer quality, local healthcare services that the local population needs.

Our facility has a proven record in providing outpatient services to our community with general supervision from our local physicians. General supervision does result in positive patient outcomes and allows us to deliver the services that are essential to our community.

#### CAH in Kansas

CMS's proposal to require direct supervision for outpatient services for CAH's and small rural hospitals is in direct conflict with the intent of the CAH program, which allows CAH's to operate with providers being available on site within 30 minutes. Requiring direct supervision for services that have traditionally been provided safely by Registered Nurses or non-physician providers under general supervision may limit the ability of CAH's to provide services they have traditionally provided to their communities. Although we are currently positioned to be able to provide services under the proposed rule due to our staffing of our ED with physicians, we, and many other CAH's may not always be in position to do so. Even having 24/7 physician coverage in the ED does not ensure that we will be able to meet the requirements for direct supervision should we have the need for that physician at a time he or she is unavailable due to an emergency.

For CAH's and small rural hospitals, CMS needs to be flexible in its interpretation of "direct supervision" to allow for emergency care of patients when a physician is not immediately available. If a patient presents to the ED in cardiac arrest, and there is no provider in house, the nurses should be able to initiate ACLS protocol and administer treatment until the provider arrives (up to 30 minutes for rural CAH's and up to 60 minutes for frontier CAH's).

Recruiting primary care providers to practice in rural areas is extremely difficult, and the days of the physician being on call to see his/her patients 24/7 are over. Young physicians seek and deserve work-life balance, and many rural hospitals are not in a position to provide in house or on-call coverage relief that meets the requirements of today's physicians. Thus, they will have to limit services that require direct or personal supervision unless non-physician providers are allowed to perform supervision of those services, and then, for some very rural and frontier CAH's and small rural hospitals, recruiting non-physician providers is as difficult as recruiting physicians.

CMS should ensure that, for CAHs, the definition of "direct supervision" is consistent with the CAH conditions of participation that allow a physician or NPP to present within 30 minutes of being called to come to the hospital.

CMS should set general supervision as the default for outpatient therapeutic services with the exception of a very few procedures that require direct and personal supervision, such as nuclear stress testing.

#### CAH in Kansas

The accessibility for our patients would definitely be reduced under a removal of the moratorium for direct physician supervision. Accessibility would be limited during evenings and weekends which would again cost small hospitals more money in a declining reimbursement scenario. The cost would come in the form of paying our physicians more money (if we could get them) and our staff to work extra hours in the evenings and on weekends.

This regulation was most likely intended for large hospitals whose physicians may not be readily available. Guidelines such as this are not a one size fits all and consideration must be given for small hospital procedures and availability. Even if we are not allowed to perform such procedures our patients would most likely have trouble getting access to the larger medical centers and would have trouble traveling (in some cases) to those locations. Cost for these patients would increase and accessibility reduced. This is not good medicine.

Once again, not good medicine. If our providers must provide immediate availability, this means they cannot see patients in our Rural Health Clinic or treat patients in our ER. We do not have the resources or the manpower to offset the removal of this moratorium.

Regarding Number 2 asking about specific services that we might have difficulty furnishing, here are our comments. Outpatient drug infusions, blood transfusions, PICC line product transfusions and other direct supervision modalities. These are critically needed procedures that accessibility will be reduced if the moratorium is lifted. Rural healthcare comprises less than 5% of the healthcare budget. Quit trying to save money and let's provide service to our rural patients.

#### CAH in Kansas

We are in a small community of less than 2000 people and have just recently added another mid-level practitioner to our clinic staff which brings us up to 2. The addition of this new practitioner has been a life saver for the other practitioner already in the clinic. It is hard to be able to see patients and cover call without some help. They are needed in the clinic to see patients, not in the hospital sitting around watching our staff do their jobs. If this comes to pass, we might as well not offer these types services anymore because we will not have a physician or other practitioner able to come over and sit around in these various departments to oversee these services being done. Their qualifications are better served in the clinic setting where they can see people who are ill and have other medical problems that need to be dealt with. The time in the clinic they can be paid for, whereas I don't believe they would get paid for sitting around at the hospital overseeing our services being given. To me this is a slap in the face to our professionals in the hospital who went to school and are trained to take care of patients in the fields they are in. If this comes to pass, it's like saying we don't trust you to deliver care without the physician standing by. If it has worked all these years the way it's been, then there is no reason it won't continue to work.

## CAH in Nebraska

Physicians providing care in a rural Critical Access Hospital face different obstacles than those providing healthcare services in a urban setting and requires a different skill set.

At XX Hospital we have 5 family practice physicians. We rotate our weekend emergency call on a one-weekend-in-five basis. The weekend call starts at 6 p.m. on Friday night and goes until 7 a.m. on Monday morning. We rotate weekday evening call on a 1 in 8 rotation, sharing primary call with our 3 physician assistants. Backup call for the PAs is shared on a 1 in 5 basis. We all do OB. Two of us perform C-Sections and those two rotate that call.

Our Critical Access Hospital Conditions of Participation (COP) in Medicare require that we are immediately available by phone and available on site within 30 minutes. The direct supervision rules are actually in direct contradiction to the COPs. All of us live within our service area, allowing us to respond within that timeframe. We practice in a rural setting because we like the lifestyle and the hard working people. The extra burden is unwarranted.

The proposed Outpatient Therapeutic Physician Supervision Guidelines put a burden on us that doesn't improve the quality of care. These guidelines require us to spend more time than necessary at the hospital supervising things that our nurses and therapists have been doing well for years and without incident. These therapeutic services are also within their scope of practice.

As we're sure that you are all aware, there is a shortage of primary care providers in the U.S., especially in the rural areas. This shortage is only predicted to worsen in the next few years.

The outpatient physician supervision rules only make it harder to recruit physicians to the rural area and make it less attractive for young people to go into rural medicine. Two of my sons are contemplating family medicine. These supervision rules will not help. A balanced lifestyle is very important to our younger physicians and the rest of us as our families grow and are involved in numerous activities.

The direct supervision requirement will be difficult to implement for Critical Access Hospitals and it is clinically unnecessary. It would require us to have more practitioners available to meet these requirements, if we could afford them and could recruit them. Where is the clear clinical need?

General supervision, as we have always had, makes much more sense. We still have the clinical responsibility but the non-physician staff can perform the services that they have been trained to do. Our hospital has twice been named to the Top 100 Critical Access Hospitals in the country (using quality, cost and outcomes analytics) and our HCAHPS survey scores are consistently in the 90th percentile for patient satisfaction (most recently the 93rd percentile).

Specific services at risk:

- 1) Blood transfusions (having to wait until morning for a physician to be physically present when lab results indicate a unit or more is needed---cross matching is done on every unit and

nurses are well aware of any potential risk and how to handle them---and the physician can be present immediately by phone and physically within 30 minutes, just like any emergency)

2) Outpatient observation patients, once they've been seen either in ER or in one of our clinics--physician has seen the patient and made the decision to put them in OP observation to perform ancillary services to determine a diagnosis from the symptoms observed on initial visit

### CAH in Nebraska

Our biggest fear in all of this is what happens to our outpatient observation stays. Will we be able to continue to provide that service? XX Hospital is 50+ miles away from the nearest tertiary facility. Given that distance, we are forced to have the observation program in place in order to keep the patient and their families close to home while they wait for a test result for example. On average, XX Hospital probably totals about 100 patients and 2000 hours of observation time. Without that program, my assumption would be that all of those patients would have been admitted into the hospital as way to keep tabs on their condition. Given the major cost difference we have between that observation and acute care, the loss of this type of service will significantly increase the cost of care to the patient.

As a CAH located in a town of 1200 people in Nebraska, we are very fortunate to have the one physician we do on campus. This physician is here in clinic for 4.5 days per week. Using last week as an example, he was out on vacation. Did the patients quit coming during that time? No. That is why we must push for CMS to allow us to use the same rules we have for ER call coverage. Our facility always has either an MD or mid-level provider on staff 24/7 to cover the ER. He or she is required to respond within 30 minutes. Also, we always have an MD on call to backup any of the mid-level providers. We have to be able to use these rules going forward. Every CAH will suffer if that's no longer the case.

### CAH in Nebraska

We are writing out of concern for XX Hospital relative to the outpatient supervision rules due to be enforced beginning January 1, 2014. XX Hospital is a critical access hospital with three family practice physicians and three physician assistants on staff. Compliance with the rules governing outpatient supervision will pose a significant hardship that will be very difficult for the medical staff.

The extra time demands to meet the supervision requirements as it stands would require the hiring of additional staff. It would be physically unreasonable for the present local staff to attend patients throughout the night and see a full schedule of patients the next day. At this time, it would be very difficult to hire additional primary care staff that is already in short supply. We would need to hire an additional 3 FTE's to meet the provider requirement. Without the extra staffing we would transfer the patients needing observation and or the relevant intravenous infusions. The closest hospital having twenty-four hour per day provider staffing is two and one-half hours away. This would be a physical, emotional, and financial hardship for the patient as well as the family.

It is the unanimous consensus of the XX Hospital Medical Staff that the outpatient rules governing patient observation admission and the hourly stay should require the same provider availability as the rules applying to the emergency room for critical access hospitals. Also, the

requirements for CPT codes 96365, 96367, 96368, 96374, and 96375 should also be changed to be the same as the emergency room response requirements.

Again, it is the firm belief of XX Hospital and the XX Hospital Medical Staff that the enforcement of the physician supervision requirements is clinically unnecessary and would pose a significant hardship to the local medical staff.

#### PPS hospitals in Nebraska

Our concerns at both XX Medical Center and XX Hospital relate to the enforcement of the physician supervision requirements center on Radiation Oncology. From the CMS perspective, Radiation Oncology falls under the Direct Supervision requirement, which requires the immediate availability of a physician or NPP to supervise the service. The supervising provider is supposed to be able to, with their knowledge, credentialing, and scope of practice, respond to emergencies and also to have the training and credentials to take over performance of a procedure and, as appropriate, to change a procedure or the course of care for a particular patient. Providing direction and assistance of this nature in Radiation Oncology requires specialized training that is outside the scope of most non-Radiation-Oncology-trained physicians.

Additionally, our understanding of the Nebraska scope of practice for both APRNs and PAs is that Radiation Oncology falls outside their scope of practice, which excludes them from being able to be the supervising provider for Radiation Oncology procedures. That means a Radiation Oncologist would need to be immediately available whenever Radiation Oncology therapy is being provided.

Other local hospitals only have one Radiation Oncologist in each community. The enforcement of the supervision requirements will therefore limit the ability of both XX Medical Center and XX Hospital to provide Radiation Oncology services to the dates and times when the sole physician in each community is immediately available to provide services. Our hospitals will need to either recruit additional Radiation Oncologists to our respective communities or limit the availability of services to patients in order to meet the supervision requirements. Adding another physician will add significant cost and reducing services will limit access to appropriate, necessary care for patients. As you are well aware, adding costs and reducing access are both detrimental to healthcare in our country. An additional challenge is that the low number of Radiation Oncologists in the nation will severely limit the ability to recruit additional physicians.

#### CAH in Nebraska

Our biggest issue with the direct supervision rule is as it pertains to observation patients. If I understand correctly, when we admit a patient to observation, the requirement is direct supervision until the patient is stabilized. Meaning, one of our providers needs to be at the facility, immediately accessible. When a very small rural facility like ours that operates with a part-time MD and two mid-level providers admits to observation, it will be a heavy burden on the provider, who most likely will also be working clinic during the day, to be immediately available all night at the hospital. Also, it will pose a heavy financial burden on the facility to pay that provider to be at the facility.

### CAH in Illinois

As a CAH, we would have extreme difficulty in furnishing the required direct supervision to cardiac rehab, pulmonary services, outpatient blood and drug infusions. This would cause us to have to limit our hours of operation in all of these areas based upon physician schedules and availability. This will create a huge dissatisfier for patients and will reduce revenue in these departments.

### Small Rural PPS Hospital in Iowa

In response to the questions in your email, ending the moratorium on direct supervision would have a huge impact for the patients we serve at XX Medical Center. Services that would be impacted are chemo, outpatient infusions, and Cardiac Rehab. We have a visiting oncologist from Des Moines one day per week that establishes the regime for chemo. Our patients are in compromised health and the 60-70 mile trip on a daily or weekly basis could greatly impact their already limited stamina. Many of our outpatient infusions patients are elderly and cannot drive themselves or find rides to make the 60-70 mile trips. Other outpatient infusion patients are working and we can offer times to meet their break times or before/after work. The majority of our Cardiac Rehab patients are from Des Moines or Iowa City referrals back to their community (xx Hospital service area). Not having this service would decrease patient compliance as we offer a schedule that they are willing or able to meet. Adding a minimum of 2 hours of travel time could result in them not participating in a program.

We currently have 2 physicians that provide supervision for cardiac rehab who are in the same building, but 2 floors away. Our Internal Med hospitalists provide oversight for our chemo patients 4 days a week (oncologist here 1 day a week). They are in the hospital whenever chemo is being administered. Changing the rules/ending the moratorium has the greatest impact on the patients involved, causing undo expense and time of travel as well as the physical impact it would have on their compromised conditions. I feel we have the necessary available supervision to provide safe and economical care. We take great pride in providing these services to our community not because of financial gain (barely break even services). We provide these services because it is our mission to provide care and service to people in our community/service area.