



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

April 3, 2013

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

Re: CMS 3267-P, Medicare and Medicaid Programs; Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Proposed Rule, Feb. 7, 2013

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to revise and clarify certain existing Medicare regulations that the agency has identified as unnecessary, obsolete or excessively burdensome on health care providers.

We commend CMS for continuing to identify outdated and burdensome regulations and for seeking ways to update Medicare requirements and streamline the delivery of health care. While we support many of CMS's proposed changes, we oppose the agency's intention to preclude the leaders and medical staffs of some multi-hospital systems from implementing a single unified, integrated medical staff structure. We believe that CMS should allow multi-hospital system leaders and medical staffs to decide, together, which medical staff structure best enables them to deliver high-quality care for their patients and communities.

Given the continuously changing nature of health care and the science that supports safe, effective delivery of care, the AHA encourages CMS to make regular review of its requirements a priority, as outdated regulations can become obstacles when it comes to the adoption of the most advanced approaches to medicine.

Our detailed comments on the proposed rule follow.



HOSPITALS: GOVERNING BODY

We support CMS's proposal to eliminate the requirement that a hospital governing body must include a member of the medical staff. In October 2011, CMS issued a proposed rule that included a provision to allow multi-hospital systems to have a single governing board. In the corresponding final rule issued in May 2012, CMS adopted that provision and also included an additional requirement, which had not been proposed, that the governing board must include a member of the medical staff. As noted in our June 5, 2012, letter to CMS responding to the May 2012 final rule, although many hospitals already include a member of the medical staff on their governing boards, the additional requirement was not practical for a number of reasons. For example, some governing boards are publicly elected or appointed by city or county officials. Further, in Iowa, the law prohibits a medical staff member from serving as a trustee of a county public hospital. In addition, investor-owned hospitals have governing boards selected by their investors, and it is not appropriate for an agency to interfere with choices made by investors in a privately held company.

We are pleased that CMS's Feb. 7 rule proposes to eliminate the requirement that a hospital governing body include a member of the medical staff, and rather would require hospital governing bodies to periodically consult directly with the individual responsible for the organization and conduct of the medical staff, or his or her designee. Under this framework, hospital governing boards would need to consult at least twice a year with their designated medical staff representative, and unified governing boards of multi-hospital systems would be required to consult with a medical staff representative from each hospital in the system.

We appreciate CMS's intention to foster communication between the governing body of a hospital and its medical staff. Effective communication between governing boards and medical staff leadership, especially with regard to quality of care, is vitally important. However, many of our members are confused about what type of consultation CMS would consider as meeting this requirement. It would be helpful if CMS could provide a few examples in its final rule. For example, we assume that if a member of the medical staff served on the hospital board or was a liaison to the board, as CMS originally proposed, that would constitute the type of communication CMS envisions. Other hospitals might choose to have the quality or operations committee of the board engage with the medical staff leaders of the hospital (or hospitals in a multi-hospital system) in meetings designed specifically to discuss quality and safety. We assume that this option is acceptable as well.

However, for systems with large numbers of hospitals and a single governing board, requiring separate consultations between each medical staff representative and the entire governing board would prove unworkable. Under this scenario, for example, the governing board of a hospital system comprised of 25 hospitals would be required to participate in at least 50 consultations per year. We suggest that CMS clarify that the options through which a hospital can comply with this provision include, but are not limited to: (1) designating a subcommittee to carry out these consultations, and (2) communicating with multiple medical staff representatives simultaneously.

HOSPITALS: MEDICAL STAFF

In its Feb. 7 proposed rule, CMS states that it intends to modify the language of the medical staff CoPs to require each hospital to have its own distinct medical staff. CMS defines hospitals by provider agreement, which is tracked by a CMS Certification Number (CCN). Therefore, this proposal would require all hospitals with their own provider agreements, even those that are part of multi-hospital systems, to have their own medical staffs. At the same time, it would require each multi-hospital system certified under one provider agreement to have a single unified, integrated medical staff across all hospitals in the system.

We urge CMS to reject this proposal. CMS should allow multi-hospital system leaders and medical staffs to decide, together, which medical staff structure best enables them to deliver high-quality care. Instead of prescribing a particular medical staff model, CMS should focus on standards to ensure medical staff self-governance and effective communication throughout the medical staff, and between the medical staff and the governing board.

CMS's proposal is arbitrary, ignores the benefits that integrated medical staffs can achieve for patients, and disregards the sizeable burden that dismantling a unified medical staff structure will impose upon multi-hospital systems already operating in this manner. Further, CMS should recognize that the decision to organize multiple hospitals under a single provider agreement can have a wide range of ramifications and may not always be in the best interest of patients, communities and hospitals. We believe CMS should concentrate less on structure and more on policies to ensure that patient safety goals are met.

CMS's Proposal Creates Arbitrary Policies. CMS's proposal would substitute the agency's judgment about how the medical staff should be organized and governed for that of the medical staff at each hospital, undermining the concept of self-governance. In each case where there is currently a unified medical staff, the members of the medical staff chose to organize themselves as a unified body, amending their medical staff bylaws in accordance with the required procedures and processes. CMS would require some of these unified medical staffs to completely dismantle their structures *without any substantive data to support why this change is necessary*. In the proposed rule, CMS offers no evidence to demonstrate that it has thoughtfully evaluated the provision's merits or impacts. Thus, without appropriate justification, effective and engaged medical staffs that are currently working well will have to change their organizations, revamp their bylaws and associated documents, and reorganize themselves into a structure that makes it harder to recapture the benefits the medical staff achieved when it chose to unify.

CMS's proposal would result in an arbitrary and inconsistent application of Medicare regulations. CMS would base the decision of whether a multi-hospital system may have an integrated medical staff on the mechanics of how its provider agreement is structured, rather than on an evaluation of the best structure for that system. Further, while the proposal would require each separately certified medical staff to have its own medical staff, it would actually require hospitals organized under one CCN, a phenomenon CMS calls a "multi-campus system," to have

a single integrated medical staff. The proposal would even force a hospital that is physically located within a larger hospital and that has a separate CCN to have a distinct and separate medical staff.

This proposal also stands in stark contrast to the goal of integrated health care delivery as envisioned in the *Patient Protection and Affordable Care Act (ACA)*. Since passage of the ACA, the Department of Health and Human Services (HHS) has established the Center for Medicare and Medicaid Innovation (CMMI) to evaluate coordinated care delivery models, approved hundreds of accountable care organizations (ACOs) and promoted medical homes. Even when hospitals choose not to pursue new types of payment and service delivery redesigns, they are more effectively coordinating care across the continuum, motivated in part by ACA provisions such as the readmissions payment penalty program and efforts to reduce hospital-acquired conditions (HACs). Further, not only is the government encouraging greater integration of care, but private-sector payers, employers and patient advocacy groups are driving change in the same direction. In order to encourage all parties to work together to achieve care coordination, hospitals must restructure themselves in different ways. Some have chosen to make the integration of the medical staff part of that restructuring, because they believe it is most effective for their organization and the communities they serve. Given the widespread recognition that integrated approaches to care delivery are essential to the future of health care, the CoPs should not require medical staffs to operate in silos.

Unified Medical Staffs Can Offer Patient Quality and Safety Benefits. There is no single medical staff structure that works best in every situation to ensure the highest quality of care. However, within some hospital systems, medical staffs have embraced a unified structure with the goal of improving patient care and safety. By adopting an integrated medical staff framework, these systems were able to achieve high standards of care consistently throughout the enterprise.

Unified medical staffs can have a powerful advantage in the advancement of patient safety improvement initiatives, such as those adopted by thousands of hospitals participating in the HHS's Partnership for Patients campaign. Fundamental to any harm reduction strategy is the need to ensure that evidence-based practices are adopted in a consistent, standardized way. Multi-hospital systems strive to ensure that best practices are employed uniformly across their facilities and can measure and benchmark the progress on a system-wide basis.

For example, a unified medical staff within such a system may agree to address early elective deliveries by establishing hard stops at each hospital, with the goal of reducing the rate of early elective deliveries to 5 percent at each facility. Under a unified medical staff model, a committee of medical staff members from each hospital can conduct the research and develop an education plan, evidence-based tools, timetables and goals for this effort. The project then can be launched as part of a coordinated, system-wide initiative. In an organization with individual medical staffs, the process would likely include redundancies because the project would be implemented separately at different sites, making the sharing of knowledge and benchmarking of results more difficult. Ultimately, each medical staff could change any aspect of the effort, such as the tools,

timetables or goals, or decline to adopt a hard stop altogether. Thus, the results at each hospital will vary for patients.

Another important advantage of a unified medical staff is that it can enhance the peer review process. Shared peer review can enable medical staffs to respond more effectively to practitioners with skill deficits. For example, in multi-hospital systems, practitioners may be privileged at more than one hospital. When medical staff members identify deficiencies with a practitioner at one hospital, that hospital's medical staff, if separate, can modify only the practitioner's privileges at its own facility but cannot share information with the medical staffs at other hospitals in the system. Thus, patients at other system-affiliated hospitals may continue to be treated by the practitioner. Shared privileging through a unified structure would protect patients. In addition, with a unified medical staff, physicians may be less likely to be in the same practice, or competing practices, with the practitioners whom they evaluate during peer review. While it is possible that variations in practice may exist due to differences in the patient populations served by different hospitals, or due to differences in available resources, the characteristics particular to each hospital and each patient population can be addressed during the peer review processes when there is a unified medical staff.

Hospitals can realize other patient benefits through integrated medical staffs. Several hospitals have pointed out to us that unified medical staffs can achieve better call coverage for specialties in short supply. Thus, care for patients in the emergency department, for example, may be enhanced because of a larger pool of practitioners and specialists to call for consultations. A unified medical staff is also helpful when practitioners have privileges at multiple hospitals in the system, because they do not need to attend the same meetings at different facilities, and there is less variation in procedures and practices at different hospitals that can create confusion and contribute to mistakes. In addition, peer review and Ongoing Professional Practice Evaluation (OPPE) can be enhanced because the pool of experts who can coach their colleagues is larger. Further, integrated medical staffs can more easily coordinate community health and service planning. Finally, integrated medical staffs can help standardize decision support in electronic medical records.

Under the current proposal, medical staffs that have established unified structures would lose some of these benefits and would be forced to create less efficient mechanisms in an attempt to regain them. We believe that CMS should allow hospital leaders and medical staffs to weigh the benefits and drawbacks of a variety of structures and to choose a framework they decide upon together, based on their firsthand knowledge and the circumstances of their patients, locations and community resources.

Quality Performance. CMS emphatically states in the preamble that separate medical staffs are better for patients, but we find no evidence to support this assertion. In fact, we note that a number of the organizations with unified medical staffs have been lauded for their quality, with some appearing among the top hospitals or health systems listed in *US News and World Report*, being awarded designation as primary stroke centers by The Joint Commission, receiving a gold award from the American Heart Association, or receiving an award for performance on Get With the Guidelines from the American College of Cardiology. When we look at CMS's own publicly

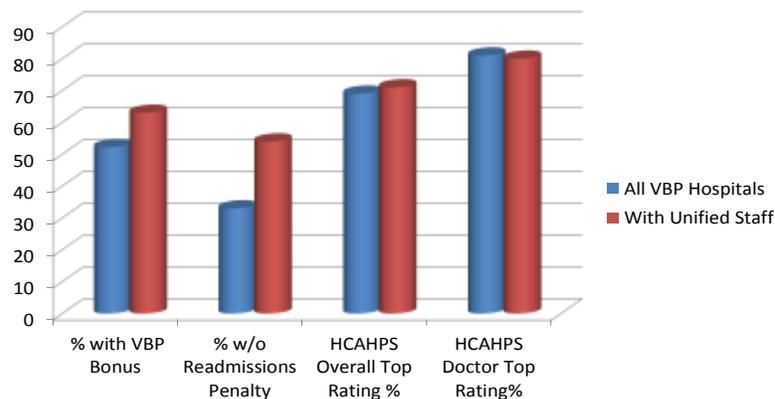
shared data, we find that the organizations with unified medical staffs, on average, are able to achieve results that are at least as good, if not better, than other hospitals.

As shown in the chart below, we compared the 35 hospitals that we have been able to identify through communications with our members as having unified medical staffs to the rest of the hospitals that are eligible for the payment incentive programs of Value-Based Purchasing or the Readmissions Reduction Penalty Program. Specifically, we looked at the proportion of hospitals in each group that received value-based purchasing incentives for performance on critical quality measures, the proportion of hospitals receiving readmissions penalties, the proportion of hospitals with the highest rankings for overall hospital rating on the HCAHPS survey, and the proportion of hospitals with the highest scores on the HCAHPS question on communication with the patient’s doctors. We found that those hospitals with unified medical staffs are:

- More likely to receive a value-based purchasing bonus (52 percent of all participating hospitals got a bonus, compared to 63 percent with a unified medical staff);
- Less likely to receive a readmissions penalty (33 percent of all participating hospitals escaped without a penalty compared to 54 percent of those with unified medical staffs);
- Equally effective in achieving an overall high rating from their consumers (69 percent of all hospitals got “top box scores” for the overall rating compared to 71 percent of those with a unified medical staff); and,
- Nearly as likely to receive high marks for the way their doctors communicate with patients (81 percent of all hospitals received “top box” scores for physician communication, and 80 percent of those with a unified medical staff received such scores).

If physicians or others were disgruntled with the medical staff arrangement, or if unification of the medical staff were to impede quality, it should be visible in some of these metrics, but it is not. We know that there are other hospitals with unified medical staffs, but at the moment, we do not have available mechanisms to identify and include them in these data.

Quality Performance: Hospital With Unified Medical Staff Compared to All VBP Hospitals



Integrated Medical Staffs Maintain Self-Governance. If a hospital system with separately certified hospitals wishes to adopt an integrated medical staff structure, the medical staff of each hospital must be in agreement. The assertion by someone who commented on the 2011 proposed rule on CoPs that a hospital's medical staff could be disbanded by the unilateral decision of a multi-hospital system is simply untrue. Under Medicare requirements, the bylaws outlining the structure of the medical staff are adopted by the medical staff and approved by the governing body. Thus, the choice to move to a unified structure would be a joint decision. The same is true for requirements of The Joint Commission. In fact, MS.01.01.03 requires that, "Neither the organized medical staff nor the governing body may unilaterally amend the medical staff bylaws or rules and regulations."

There is also no truth to the claim that because a medical staff is integrated it somehow loses the ability to be self-governing. Unified medical staffs develop bylaws that describe their processes for self-governance and detail their structures, committees and policies for appointment to the medical staff. We understand that concerns exist with regard to ensuring that medical staff members at smaller hospitals continue to have a meaningful voice within an integrated medical staff model and can respond to the needs of their own patients. Unified medical staffs have been structured to take into account each hospital's unique circumstances and to ensure that the voices of members of the medical staff, regardless of practice or location, are heard.

For example, Greenville Hospital System in South Carolina uses a framework for performance improvement in which medical directors representing each department of each hospital in its system work with a centralized performance improvement committee. This structure allows for integration and communication from each hospital. Specific hospital issues are resolved by the practitioners at those hospitals, who understand the patients' requirements.

In fact, the systems we have spoken with offer many mechanisms for individual physician involvement and feedback, such as a centralized Medical Executive Committee (MEC) made up of elected representatives from each hospital's own MEC. In addition, hospital systems have other committees, such as pharmacy and therapeutics committees, at each hospital that feed up to a centralized committee that plays a coordinating role. Thus, a balance can exist allowing integration as well as local direction and management. As Greenville Hospital System and others demonstrate, integration is compatible with self-governance.

Hospital systems repeatedly express to us that they want physicians to be involved and seek ways to encourage their participation. Further, the participation of medical staff members from each hospital can be measured, through documentation of organizational policies and procedures, committee structures and meeting minutes, for example. Many hospitals also conduct medical staff satisfaction surveys.

Dismantling a Unified Medical Staff Will Impose Significant Burden. We cannot underscore enough that the process of dismantling a unified medical staff structure into multiple and separate independently functioning medical staffs imposes a huge burden on medical staffs and hospital systems. Some unified staffs have operated within some systems for decades, and medical staff leaders would need to break apart all of their structures, policies and procedures

and recreate structures, policies and procedures at each hospital. **CMS should not impose this level of burden upon medical staffs without strong evidence that the benefits of doing so outweigh the disadvantages to hospitals, medical staffs and patients.**

Under the proposal, the new medical staff leadership at each hospital would need to identify people to draft the bylaws and develop a timetable and work plan for the development and adoption of the bylaws. The work plan would include lengthy deliberations among the drafting committee and the medical staff leadership and would likely include seeking input from individual medical staff members as well as legal counsel. It also might include coordination with medical staff leaders throughout the system if leaders wished to maintain standardization among the hospitals.

Through these deliberations, the new medical staff would need to establish the process for the election of medical staff leadership, the criteria for medical staff membership, and the qualifications of department chairs. The bylaws also would need to address what committees would exist, such as an executive committee, a pharmacy committee, a medical records committee, a quality improvement committee and a peer review committee. They would have to determine the roles, responsibilities and functions of each of these committees and how they would be staffed. Further, the bylaws would need to address the peer review process, the criteria and process for disciplinary actions, and how the bylaws can be amended. In each of these steps, the new medical staff leadership would need to consider how the medical staff would function in these areas differently than before and what new resources would be needed to support an independently functioning medical staff. Maintaining separate medical staffs at each hospital would require significant resources to manage individual processes such as OPPE and operate numerous medical staff committees and meetings. These hospitals may also incur software and related expenses.

After working to gain consensus on these and other matters, the new medical staff leadership at each hospital would need to shepherd these changes through the adoption process, which could include a comment period and time for revision, and ensure enough staff members vote. In addition, parallel activities might be taking place to break down, perhaps formally, the old structures, and hospitals would need to take measures to ensure continuity during this time of change.

At the same time, governing boards would need to review and approve multiple sets of bylaws and, on an ongoing basis, continue to review multiple sets of bylaws amendments. Further, the governing board would need to adopt changes of its own to implement new communication and coordination mechanisms with each new separate medical staff.

Organizing Under a Single Provider Agreement May Be Impractical. CMS has asked why systems with hospitals in close proximity to one another do not simply organize under one provider agreement to avail themselves of the benefits of a unified medical staff. When evaluating a move to consolidate hospitals under a single provider agreement, hospital systems must examine all of the consequences, which means analyzing all legal, regulatory, financial and licensure effects, as well as the community impacts. After evaluating all of the potential impacts,

hospital systems often conclude that it is not in the best interest of the patients, the communities and the hospitals to organize under separate provider agreements.

For example, hospitals could lose important resources to care for low-income patients by organizing under a single provider agreement. A hospital's Disproportionate Share Hospital (DSH) funding is linked to its CCN. The formula used to determine DSH funding is based on the portion of a hospital's Medicare patient population that is eligible for Supplemental Security Income (SSI) as well as the portion of its total patient population eligible for Medicaid. This formula is applied separately to each CCN. If multiple hospitals merge together, the formula is then applied to all of the hospitals under that CCN, which could yield very different results than when it is applied separately to each hospital. For example, if Hospital A, which receives DSH payments, merges CCNs with Hospital B, which does not because it serves very few SSI and Medicaid patients, the combined entity will not necessarily maintain Hospital A's DSH funding. Rather, it is possible that the combined entity would not receive any DSH payments at all because it would not reach the qualifying SSI/Medicaid threshold.

Meaningful use incentives, which help hospitals modernize their operations to improve care and efficiency, are also allocated to hospitals based upon provider agreement. The base incentive for a hospital with a single provider agreement is \$2 million. If a health care system with three hospitals organized under one provider agreement, the base meaningful use incentives would decline from \$6 million to \$2 million. Given the extraordinary costs associated with adopting electronic health record systems, it would be challenging to eliminate this critical resource. Meaningful use penalties will also be assessed by provider agreement, meaning that if one hospital in a group that is organized under a single provider agreement lags behind, it could easily decrease the group's collective performance on the meaningful use indicators, resulting in a significant penalty for all hospitals in the group.

Organizing under a single provider agreement also could pose a dilemma with regard to enforcement actions by state survey agencies. When a hospital is cited for the most serious deficiency, an immediate jeopardy, the hospital is put on a 23-day track for termination of its provider agreement. That means that all of the hospitals under that same provider agreement could face termination from participation in the Medicare program. That scenario has profound implications for the patients of the entire hospital system, and this risk is of serious concern to hospital and medical staff leaders.

Communities also can be impacted when hospitals organize under a single provider agreement. For example, all hospitals certified under a single provider agreement must have the same name, although they can have derivative versions of the same name. In small communities, where the hospital has been a part of the identity of the community and the name of the hospital conveys a certain brand associated with the community's values, changing a name can create discord.

These examples illustrate a few of the potential impacts that systems must consider when evaluating whether to organize under one provider agreement. The analysis also may include how a consolidation would work under state law regulations, whether agreements with other payers, such as private insurance companies, would be negatively impacted, how any hospitals

with religious affiliations might be affected, whether the cultures of the hospitals are compatible, if indirect medical education payments will change, and if there would be federal and state tax implications.

CMS Should Redirect its Focus to Communication, Self-Governance. We believe that CMS has focused on the wrong question with regard to whether a medical staff can be unified under the CoPs. The AHA believes CMS should defer to hospital leaders and medical staffs to determine their own structures. Rather, CMS should emphasize what unified medical staffs need to do to demonstrate that the needs of each hospital in the system are met and that the medical staff members of each hospital have mechanisms through which they may self-govern and voice their concerns and ideas.

We recommend that CMS review the leadership standards for Joint Commission accreditation. Our members and others have lauded The Joint Commission's leadership chapter as providing the right framework for an effective relationship among hospital governance, hospital management and the medical staff. The leadership chapter emphasizes that leaders from all groups should be able to participate in discussions and have their voices heard. It also encourages a culture of honest and open communication to ensure for the safety and quality of care.

In a similar vein, CMS could issue guidance with respect to its expectations of unified medical staffs to ensure that the goals of effective communication, participation and self-governance are met. For example, surveyors could ask to see the bylaws, policies and procedures of the unified medical staff that allow for self-governance and active participation by all medical staff members. Surveyors could interview medical staff leaders to ask for examples of how their members are involved in decision-making and how they are able to protect the individual needs of their hospitals. Additionally, medical staff leaders at hospitals can be asked during a survey if they feel their voices are heard within the unified medical staff structure. Thus, there exist a multitude of ways to address the concerns about self-governance and meaningful input.

CMS Should Reject the Medical Staff Proposal. In conclusion, we reiterate that the proposed medical staff provision is arbitrary in application and completely out of step with the current move towards integrated care, ignores potential patient safety and quality of care benefits that may be achieved through unified medical staffs, and would impose significant burden on hospitals that would have to break down their existing medical staff structures. Further, CMS proposes to adopt such a provision without any evidence that separate medical staffs are better at achieving high-quality care. CMS should reject its proposal and rather focus on how to ensure medical staffs communicate effectively with regard to patient safety and quality of care.

HOSPITALS: FOOD AND DIETETIC SERVICE

Current regulations require that therapeutic diets may be ordered only by practitioners responsible for the care of the patient, which CMS views primarily as the physician, and to a lesser extent, the advanced practice registered nurse (APRN) and physician assistant (PA). CMS proposes to revise the regulations to state that all patient diets, including therapeutic diets, must

be ordered by a practitioner responsible for the care of the patient, *or by a qualified dietician as authorized by the medical staff in accordance with state law*. The AHA has received very positive feedback from members who believe this change will have a positive impact on care and will ensure more timely and appropriate diets for patients. **Therefore, we support this change to allow qualified dieticians to order patient diets as authorized by the medical staff and in accordance with state law.**

HOSPITALS: NUCLEAR MEDICINE SERVICES

Currently, hospitals must provide for direct supervision by an appropriately trained registered pharmacist or a doctor of medicine or osteopathy for the in-house preparation of all radiopharmaceuticals. Direct supervision means that the pharmacist or doctor must be present and available at the hospital. CMS proposes to remove the word “direct” from the current regulations. In this way, supervision would be required, but the supervising doctor or pharmacist would not need to be on site 24 hours per day. The AHA also received positive feedback from its members regarding this proposed policy change. **Therefore, we support the removal of the requirement for direct supervision.**

HOSPITALS: OUTPATIENT SERVICES

CMS proposes to add regulatory language to the outpatient services CoPs to clarify who may order outpatient services. CMS proposes that orders for outpatient services may be made by any practitioner who is:

- Responsible for the care of the patient;
- Licensed in the state where he or she provides care to the patient;
- Acting within his or her scope of practice under state law; and
- Authorized in accordance with policies adopted by the medical staff, and approved by the governing body, to order applicable outpatient services.

We do not support the adoption of this new language at this time. We believe that medical staff policies defining who may order outpatient services are a good idea, and we agree that hospitals should be granted the flexibility to develop policies that allow non-privileged practitioners to order outpatient services as authorized by the medical staff and approved by the governing body. However, in conversations with hospital members in different parts of the country, it has become clear that different states vary considerably in the posting of timely and accurate information on the licensure status of doctors and other health professionals. It is not always easy for hospitals to obtain the necessary information on state scope of practice laws. This requirement could impose considerable burden on hospitals to track down information about practitioners and state laws, particularly practitioners from other states, and the process of tracking down and verifying this information could lead to delays in needed patient care. We urge CMS to first look to ensure that the infrastructure exists in states to support inquiries from hospitals, and to ensure that the information provided is reliable and up to date. Further, hospitals are not the only providers of these services, and we would note that CMS has not proposed that non-hospital providers of similar services be subject to the same requirements. If

it is not necessary for others to check licensure, then requiring this of hospitals would add burden, driving hospital costs up, and providing limited benefit to patients.

HOSPITALS: SWING BEDS

Hospitals that use some of their beds as “swing” beds (to provide patients with skilled nursing care) typically must undergo two periodic surveys: a routine survey by an accrediting organization such as The Joint Commission evaluates compliance with the hospital CoPs, while a state agency survey assesses compliance with swing-bed requirements. CMS proposes to move the swing-bed requirements from Subpart E of the CoPs (“Requirements for Specialty Hospitals”) to Subpart D (“Optional Hospital Services”). This relocation would essentially enable accrediting organizations to survey for compliance with the swing-bed regulations. **The AHA fully supports this change.**

CRITICAL ACCESS HOSPITALS (CAHs): PATIENT CARE POLICIES

Currently, CAHs must develop patient care policies with the input of professionals such as doctors, nurse practitioners, clinical nurse specialists and PAs. Additionally, the group of professionals developing the policies must include at least one person who is not a staff member of the CAH. In the preamble to the proposed rule, CMS states its belief that this requirement is no longer necessary and, in some cases, creates a burden for CAHs. Therefore, CMS proposes to remove this requirement for participation of a non-staff member. **AHA members expressed their appreciation for the elimination of this requirement, and the AHA is in full support of this proposed change.**

CAHs/RURAL HEALTH CLINICS (RHCs)/FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs): ONSITE PRESENCE OF PHYSICIAN

Currently, a doctor of medicine or osteopathy must be present at a CAH, RHC or FQHC for sufficient periods of time, at least once every two weeks (except in extraordinary circumstances), to provide medical direction, medical services, consultation and supervision. The doctor also must be available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. CMS proposes to remove the biweekly onsite requirement for these three provider types. CMS recognizes that some providers are located in extremely remote areas and that this biweekly schedule may be hard to meet. However, other requirements would still apply, such as the requirement that a doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in CAHs and that the doctor is available by radio, telephone, or electronic communication. For RHCs and FQHCs, a physician would still be required to provide medical direction and periodically review patient records, provide medical orders, and provide medical care services, among other provisions. **The AHA supports this proposed change.**

LONG-TERM CARE (LTC) FACILITIES: SPRINKLER REQUIREMENTS

In 2008, CMS adopted a requirement that all buildings with LTC facilities install automatic sprinklers throughout the building by Aug. 13, 2013. However, CMS recognizes that not all LTC facilities can meet this deadline. The proposed rule would allow LTC facilities to apply for an extension for up to two years if they are undergoing a total building replacement or major modifications in all unsprinklered living areas and that requires the movement of corridor, room, partition or structural walls to improve the living conditions for residents, in addition to the installation of a sprinkler system. These facilities would need to meet specific criteria for an extension by demonstrating that: (1) financial commitments have been made to complete the project; (2) construction plans have been submitted to, and approved by, state and local authorities; and (3) interim steps will be taken to improve fire safety during construction. The extension could be renewed for one additional year. CMS asked for comments on: (1) whether the extension should apply only when replacement buildings are constructed; and (2) what factors CMS should take into consideration when approving extensions.

We support the adoption of an extension, as well as the proposed criteria for granting such an exception. The AHA supports an extension for both LTC facilities undergoing a total building replacement and those undergoing major modifications.

We also support the requirement for LTC facilities to implement interim measures to improve fire safety of the building during construction. We note that in states or localities that have made budget cuts to their plan review departments, some applicants for the extension may be unable to meet the criteria for construction plan approval by state and local authorities by the deadline. Other factors CMS should consider in granting an extension include:

- A shortage of qualified contractors or materials in that geographic area, which may force some facilities to wait until such resources become available;
- Delays for renovation due to an abnormally high census after an unforeseen emergency or disaster in that area, which could limit access to areas for renovation; and
- The discovery during renovation of asbestos or other hazardous material requiring full abatement before sprinkler installation may proceed.

CLIA: PROFICIENCY TESTING REFERRAL

The AHA supports CMS's proposed clarification and changes to the regulations governing the prohibition of referral of proficiency testing (PT) samples. The proposed rule would create a narrowly crafted exception to current penalties under the *Clinical Laboratory Improvement Amendments of 1988* (CLIA) that would allow alternative sanctions to be imposed when there is a single instance of PT sample referral related to reflex or confirmatory testing and when the PT sample referral is consistent with the laboratory's written standard operating procedure. It also would make optional the one-year revocation of a laboratory's CLIA certificate when a laboratory has intentionally referred a PT sample to another laboratory. These changes will prevent dangerous disruptions in hospital laboratory testing services that result when the currently mandatory sanctions are imposed for referral of PT samples in situations

when personnel are merely following established laboratory protocols for reflex or confirmatory testing.

We also support the proposed rule's clarification that the current requirement to treat PT samples in the same manner as patient specimens does not mean that it is acceptable to refer PT samples to another laboratory for testing even if the laboratory's standard operating procedure calls for such referral. This will help eliminate any remaining confusion around whether the referral of PT sample is ever permitted.

After the regulation is finalized, we encourage CMS to ensure that the new provisions are implemented consistently and transparently across CMS regions and state survey agencies. In the past, there have been regional inconsistencies in the application of sanctions and in the treatment of laboratories that have had made improper PT referrals. In particular, we have learned that some regions have acted far more stringently than others for similar infractions.

In addition, we encourage CMS to clarify that the use of alternative sanctions and the other provisions for enforcement discretion included in this proposed rule may also be applied to the laboratory director. We understand that in the past there have been instances in which PT referral violations have led to the laboratory director being removed even when the laboratory was spared from the most onerous sanctions. This situation can interfere with the ability of a hospital laboratory to continue to provide critical services. Finally, because the PT referral exception described in the proposed rule appears to be so narrowly drawn, we encourage CMS to explain in more detail how in practice, the new exception will differ from the existing process, including providing scenario-based examples in the final rule.

Thank you for the opportunity to comment on this proposed rule. If you have any questions about our comments, feel free to contact me or Nancy Foster, vice president of quality and patient safety policy, at 202-626-2337 or nfoster@aha.org or Evelyn Knolle, senior associate director of policy, at (202) 626-2963 or eknolle@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President