

# HEALTH LAW UPDATE

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## MEDICARE MAY “NEVER” BE THE SAME

By Veronica A. Marsich, Attorney

On August 22, 2007, as part of the [*PPS for Inpatient Hospital Services Final Rule FY 2008*] CMS implemented a modification to its payment system for inpatient hospital services to account for what it describes as “hospital-acquired conditions”. Under this modification to the DRG payment system, Medicare has identified eight conditions which it believes should never be acquired by a patient in a hospital setting and, if acquired by a patient in a hospital setting, should never be paid for by the Medicare program.

CMS’s list of “never events” for FY 2008 includes the following:

1. Catheter - associated urinary tract infections;
2. Pressure ulcers (decubitus ulcers);
3. Serious preventable event - objects left in during surgery
4. Serious preventable event - air embolism;
5. Serious preventable event - blood incompatibility;
6. Vascular catheter - associated infection
7. Surgical site infection - mediastinitis after coronary artery bypass graft surgery; and
8. Hospital acquired injuries – fractures, dislocations, intracranial injury, crushing injury, burn, and other unspecified events of external cause.

As Medicare has designed the system, hospitals will now be expected, when they bill for an inpatient stay, to identify for each

secondary diagnosis or condition, which of those conditions were “present on admission.” This indication will be made through the use of a specifically created modifier for this purpose. With respect to any of the “never events” listed above, if those conditions are not identified as having been present on admission, Medicare will eliminate those conditions from the claim before the claim is mapped into the appropriate DRG grouping for payment.

In the Final Rule, Medicare acknowledges that there are certain instances when these “never events” can occur, despite complete and proper care having been provided to a patient. Medicare believes that, irrespective of this possibility, by denying an increased payment for these conditions when they develop following a patient’s admission to the hospital. Hospitals will be motivated to modify their delivery of care so as to avoid the development of these conditions in more instances, thereby improving the overall quality of care delivered to patients generally.

It is important to note that although hospitals will be obligated, effective January 1, 2008 to ensure that the “present on admission” modifiers are used in the context of these initial eight “never events”, payment changes for claims where these conditions are present will not begin until October 1, 2008. It is also important to note that Medicare has already identified six more conditions it intends to add to the list of “never events” for FY 2009. Hospitals should expect that the list

of “never events” will continue to grow over the next several years.

While many of the “never events” currently identified are conditions that rarely occur; and will be obvious when they do; some of these conditions, particularly catheter-related UTIs and pressure ulcers, are conditions that may very well be present in a patient on admission but not detected until several days after admission. Hospitals will need to quickly analyze how best to identify these conditions where patients as present on admission. This may be particularly challenging for teaching hospitals, which utilize residents to participate heavily in the initial patient evaluation process and may be an area or importance for hospitals that retain hospitalists to attend to most of their inpatients. Hospitals may want to consider what incentives it can create to ensure that physicians identify these conditions when present on admission. Keep in mind that errors in billing for “never events” as having been present on admission may be yet another way that hospitals can violate the Federal False Claims Act. Hospitals will need to get this right and get it right the first time.

In addition to the payment implications, there are also risk management implications associated with this change in Medicare payment policy. Now that Medicare has decided that there are certain conditions which, in its opinion, should not occur following admission to a hospital, does this mean that Medicare beneficiaries who develop one of these conditions after admission can argue that Medicare’s decision not to pay for care related to that condition is evidence that the hospital’s care did not meet the standard of care? Will courts in malpractice cases allow the introduction of evidence regarding Medicare’s payment policy as evidence of substandard care by a hospital or clinical staff? Moreover, if a hospital is not skilled in identifying conditions like pressure ulcers as “present on admission” such that its incidence of pressure ulcers developed after admission seems high in Medicare’s view, will this

trigger intense regulatory or accreditation scrutiny? Hospitals should begin to plan for who will monitor “never events” data and how will relevant information be communicated and to whom.

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One other question not answered in the Final Rule is, who pays for tests and care provided by hospitals to identify the presence of these “never events” upon admission? If lab tests are ordered to determine whether a patient has a UTI upon admission and that test is not medically necessary but only “payment necessary” then arguably it cannot be billed as part of the inpatient stay. How will hospitals identify and distinguish which of these services are billable and which are not? Similarly, if a patient develops one of these “never events” after admission, what about the professional care provided to the patient as a result of the development of the condition? If the hospital does not believe that the condition was the result of the breach of any standard of care on its part, is it appropriate to allow the physicians to bill for their care and treatment of these conditions, developed post-admission, or is the hospital obligated to pay the physicians for those services? Right now, Medicare has not given any indication that they expect the hospital to pay for the professional services associated with these “never events”. However, one might anticipate such a determination as part of a future Medical Final Rule.

Bottom line, this change in payment methodology has financial, regulatory compliance and liability implications. Hospitals that fail to consider all aspects and implications of Medicare’s “never events” payment policy risk not only damage to their bottom line but potentially damage to their reputation and credibility.

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**PART I: REVISED JOINT COMMISSION STANDARD M.S.1.20—  
THE HOSPITAL'S PERSPECTIVE  
By Adil A. Daudi, Attorney**

Standard M.S.1.20 (hereinafter "Standard") is the core Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standard which describes the expected relationship between an organized medical staff and a hospital, and which details what provisions must be included in the bylaws versus the rules and regulations of a hospital. Revisions to the Standard published on this year have generated sharp criticism from across the industry. The Standard is currently scheduled to take effect on July 1, 2009.

As acknowledged by JCAHO in its introduction to the revised Standard, the revisions are designed to impact the relationship between a hospital's governing body and its medical staff. This alert is, therefore, divided into two segments in order to address the two perspectives implicated by the revised Standard: (1) the hospital's perspective; and (2) the medical staff/physician perspective.

**BACKGROUND**

Prior to this latest revision, the last guidance from JCAHO regarding M.S.1.20 came in 2003 and 2004. Those revisions pertained to documentation requirements for medical staff procedures. This most recent revision to the Standard, issued in July 2007, has placed in doubt JCAHO's previous position that it was a hospital's and its medical staff's prerogative to address topics such as credentialing and fair hearing procedures in policies distinct from the core medical staff bylaws document.

In general, the revisions to the Standard can be broken down into two themes: (1) a mandate that certain accreditation requirements be in the medical staff bylaws; and (2) a shift in the balance between the authority of the medical executive

committee (MEC) and medical staff. Both themes impact the hospital's and medical staff/physician's perspectives on the revised Standard.

**HOSPITAL PERSPECTIVE**

From a hospital's perspective, the revised Standard has created an overly prescriptive and confusing set of rules about where and how a medical staff should define medical staff requirements, processes and procedures. Prior to the revision the determination of whether these provisions would be addressed in medical staff bylaws or other documents was left to individual medical staffs and hospital governing bodies. The revised Standard, however, now requires that certain specific matters be located in the medical staff bylaws and must be approved by the full medical staff. Specifically, the revised Standard requires that all of the following substantive issues be contained in the medical staff bylaws:

- (1) Structure of the medical staff;
- (2) Process for selecting and removing medical staff officers;
- (3) Process for selecting and removing medical executive committee members;
- (4) Process for privileging, credentialing, and appointing medical staff members;
- (5) Indications and process for disciplinary actions (suspension, termination or reduction of privileges);
- (6) Composition of the fair hearing committee;
- (7) Process for fair hearings and appeals;
- (8) Roles, responsibilities, and voting rights of each category of practitioner;
- (9) Qualifications, roles and responsibilities of department chairs;

- (10) Process for adopting and amending the medical staff bylaws, rules and regulations and policies; and
- (11) Requirements for performing medical history and physicals.

Where the various provisions are placed is important because their location determines which body can adopt and amend those provisions. In this most recent revision to the Standard, JCAHO elaborates on the already vague distinction between “processes” and “procedural details” discussed in the October 2004 Clarification. Using credentialing as an example, the revised standard provides that the “process” that must be contained in medical staff bylaws might involve steps like “collecting information on a physician, evaluating the information, and making a decision about the information.” On the other hand, the “procedural details” associated with this process might include “who collects the information, how files are kept, what organizations need to be contacted to collect all the necessary information, etc.”

An “Open Letter” submitted to JCAHO in August 2007 by concerned health care attorneys who advise hospital and physician leaders identified a number of confusing issues raised by the new Standard, particularly concerning the distinction between “processes” versus “procedural details.” For example, there are concerns surrounding the requirement that the “process for privileging licensed independent contractors” be contained in the bylaws. It is unclear from JCAHO’s “process” versus “procedural detail” distinction whether all the specific requirements to obtain privileges would need to be mentioned in the bylaws. That is, would the bylaws now have to indicate the need for a surgeon applying for privileges at a hospital to have successfully performed “x” number of a specific procedure? JCAHO has failed to identify what specific “requirements” or “criteria” must be located in the bylaws versus in separate credentialing standards (which can be

approved by the MEC and need not be subject to full approval by the medical staff).

Additionally, a similar issue arises regarding JCAHO’s mandate that the “requirements for performing medical histories and physicals be in the bylaws.” The details regarding histories and physicals (H&Ps) are typically located in medical staff rules or medical records policy. It is unclear whether the bylaws must now contain all the details regarding the content of an H&P. Moreover, if the specific requirements for H&Ps are changed, would the medical staff have to undergo the lengthy bylaw amendment process to effectuate the change? JCAHO has not offered any clarification on the potential scope and effect of mandating the “requirements for performing H&Ps” to be listed in the bylaws.

The extent of this level of prescription by JCAHO and corresponding lack of clarity is seemingly endless, as JCAHO has indicated in its revised Standard that all the requirements for EPs 9-33 must now be in the bylaws. This point raises another area of concern with respect to the JCAHO’s apparent goal of creating a more “efficient process” for creating and maintaining bylaws, rules, regulations and policies. As mentioned above, the new Standard adds a requirement that medical staff bylaws provide that the medical staff as a whole can adopt bylaws, rules, regulations, policies, and amendments, and propose them directly to the governing body. In addition, in the introduction to the Standard, JCAHO states that medical staffs are “urged” to determine what steps they will take if they do not agree with “an action” taken by the MEC.

Beyond the technical issues raised by this concept, such as the scope of a medical staff’s or an individual practitioner’s ability to override actions taken by the MEC, there are more practical difficulties with JCAHO’s revised Standard. For example, most hospitals currently struggle with simply meeting the quorum requirements to

vote on issues raised to the medical staff. Physicians often serve on multiple medical staffs. The idea these same physicians will now attend multiple regular meetings and vote on bylaw amendments is an illusion. The reality is that hospitals constantly struggle to find dedicated physician leaders to serve as committee members, medical staff officers, or in other positions of authority.

From a hospital's perspective, JCAHO has chosen to tackle these issues through overly prescriptive and, at times, unclear means. Prior to the revision, JCAHO had been comfortable with mandating the adoption of certain requirements intended to meet the needs of the hospital, medical staff, and patients. The location or manner of adoption of those requirements was not crucial, so long as the requirements were adopted by accredited hospitals. JCAHO's

overly prescriptive approach has now unearthed more questions regarding this core Standard that hospitals must now grapple with.

### CONCLUSION

Without further clarification from JCAHO, which may be forthcoming before the end of the year, hospital governing bodies should plan to make significant revisions to their medical staff bylaws, rules, regulations and other policies. The process of revising these materials often takes significant time and resources. Hospitals and their medical staffs should begin this process immediately to ensure full and timely compliance with the revised Standard.

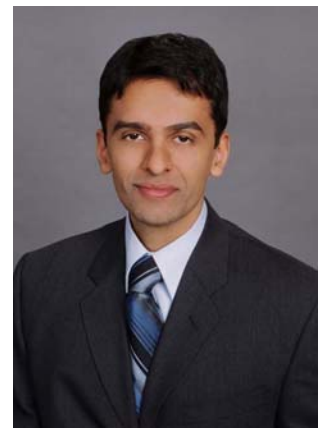
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## Who is Adil Daudi?

Adil A. Daudi is an attorney in the Ann Arbor office of Smith Haughey where he practices health law. Adil specialized in health care law during law school and was drawn to the field in part because of the complexity and unique challenges that face the industry.

“The field of health law is constantly changing,” Adil said. “I come from a family of physicians and have been surrounded by the changing face of the healthcare industry. My education in law school has taught me to recognize and analyze these changes as they arise and offer health care professionals creative and efficient solutions. The greatest counsel a lawyer practicing in health law can offer his /her client is to put the complex and changing rules and regulations in the field into simple and understandable terms. In this way, the client not only appreciates the solution I offer, but also understands how to avoid future problems.”

Adil specifically practices in the areas of Medicare and Medicaid reimbursement regulations, general corporate compliance matters including issues involving the Federal Anti-Kickback Statute and the Stark Law, and transactional health law matters particularly in the field of reimbursement, physician contracts and the confidentiality of health information.



A lawyer by day and researcher my night, Adil is a strong believer in supplementing his legal practice through the research, writing, and publication of articles pertaining to issues relevant to health care providers. Adil is an active member of the American Health Lawyers Association (AHLA) and is a regular contributor to the AHLA's Physician and Physician Organization Practice Group. He has published numerous alerts for that group's E-Newsletter Project on topics such as: progressive physician practice models, the scope of Michigan's Professional Corporation Statute, and the application of contract definitions in provider agreements. Adil has also published with the Michigan Medical Group Managers Association (MMGMA), his most recent article educated providers on the changes to the Centers for Medicare/Medicaid Services (CMS) provider enrollment rules.

Adil is a graduate of the University of Michigan and the Indiana University School of Law. He is an avid Wolverine fan, and enjoys playing tennis and basketball and spending time with friends and family in his spare time. He is active in the community and is currently serving as a Big Brother for youths of Southeast Asian descent in the Detroit metropolitan area. He is a member of the State Bar of Michigan and American Bar Association, American Health Lawyers Association and is also actively involved in the young lawyers division of the Washtenaw County Bar Association and the Oakland County Medical Society.

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