Medicare Conditions of Participation: The good, the bad and the unsure

July 10, 2012

We have been delaying issuing a Client Bulletin on the Medicare Conditions of Participation that go into effect on July 16, 2012 because there always seem to be a few flies in the soup no matter how careful the chef. Since a few flies have now been discovered, we thought it was safe to make our comments.

First, the changes apply to discrete provisions in the following areas: Governing Body, Restraints, Medical Staff, Leadership, Nursing Services, Medical Record Services, Infection Control, Outpatient Services, Transplant Center Processes, Critical Access Hospitals.

Second, most of the changes have been well-received because they appear to be doing what was proposed *i.e.*, "reducing outmoded or unnecessarily burdensome rules, and thereby increasing the ability of hospitals and CAHs to devote resources to providing high quality patient care."

Third, there is one area of concern that has become such a major issue that enforcement has been delayed - appointment of physicians to a hospital's governing body. Specifically, the "new" language provides that the governing body "must include a member, or members, of the hospital's medical staff." Concerns have been expressed that this creates conflict of interest issues, may be contrary to state law (especially as it may impact public hospitals), and a lack of notice i.e., this was not a part of the original proposed changes. So, sit tight for now.

Fourth, we have also expressed our concerns to appropriate authorities regarding the final language relating to practitioner credentialing. The original proposed language recognized that practitioners could be granted privileges without having to be appointed to the medical staff. However, the final language states that the "medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body" with no language dealing with candidates for privileges only. Further, in its comments, CMS states that it has modified this provision by "removing the proposed concept of physician and other practitioners being privileged to practice without appointment to the medical staff." At this point in time, we are not recommending any changes to current bylaws. As soon as we have clarification on this issue, we will send out another bulletin and/or E-alert.

Finally, here are the provisions that – at least as of July 1 – will be going into effect on July 16, 2012:

> Governing Body. There MAY be a single governing body for more than one provider number i.e., if your System consists of Hospital A, B, and C (each of which has its own provider number), you no longer need to have three hospital boards under the authority of a single parent board. The single parent board can now be the board of directors for Hospital A, B, and C.
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> Governing Body. There MAY NOT be a single medical staff for more than one provider number *i.e.*, if your System consists of Hospital A, B, and C (each of

which has its own provider number), you must have three separate medical staffs each of which comports with CMS standards. There is no preclusion, however, on engaging in a number of the "sharing" activities that many systems have been establishing to improve economy of actions, quality of care, etc. [Note: This is a reversal of comments that had originally been made by CMS indicating that it would recognize a single medical staff in this situation. Although "discussions" are being held, CMS has not made any change at this time.]

Restraints and Seclusion. Hospitals are no longer required to report to CMS deaths of patients in (or who have recently been in) two-point soft wrist restraints without seclusion; rather, hospitals must maintain a log of such deaths that is available to CMS upon request.

Medical Staff Composition. Language has been added recognizing the ability to appoint other categories of non-physician practitioners to the medical staff. No limits have been placed on who may be appointed (*i.e.*, appointments could range from physician assistants to dieticians) other than state law limitations. [*But see the fourth paragraph above as to whether appointments are required in order to grant privileges*.]

Medical Staff Presidents. In addition to physicians and dentists, podiatrists are now eligible to be medical staff presidents.

Nursing Services/Nursing Plans. Nursing care plans may now either be stand-alone or be part of a single interdisciplinary care plan that addresses nursing and other disciplines.

Nursing Services/Drugs and Biologicals. Drugs and biologicals may be prepared and administered on the orders of practitioners other than a physician as well as authenticated by such non-physician in accordance with state law and hospital policy.

Nursing Services/Blood Transfusions and IV Medications. This standard now provides greater deference to states and hospitals with respect to qualifications for administering blood transfusions and IV medications. The standard now provides that they must be administered in accordance with state law and approved medical staff policies and procedures.

Nursing Services/Self-administration of Medications. Hospitals may now develop patient self-administration programs for certain medications. This includes the ability of the patient (or support person) to self-administer both hospital-issued medications and the patient's own medications as specified in hospital policies. Accordingly, it is important to assure that hospital policies govern both self-administration of (a) hospital-issued medications, and (b) medications brought to the hospital by the patient.

Medical Records/Standing Orders. New rules have been added recognizing,the use of standing orders, order sets and protocols. They must be dated, timed, and authenticated promptly in the patient's medical record.

Keep in mind, however, that state law may be more restrictive with respect to the ability to use standing orders for purposes of prescriptive medicines. Check your state statutes to be sure. [*Note: Standing orders for restraint and seclusion have not been changed*.]

Medical Records/Verbal Orders. The requirement that verbal orders be authenticated within forty-eight (48) hours has been deleted. CMS will now defer to state law or a hospital's specific requirements. Further, the earlier CMS temporary provision authorizing another practitioner responsible for a patient's care to authenticate a practitioner's orders has been retained and made a part of the Conditions of Participation.

Infection Control. Hospitals are no longer required to maintain a separate infection control log.

Outpatient Services. In lieu of having a single individual acting as director of outpatient services, CMS now permits "one or more individuals" to be responsible for such services.

Transplant Center Process Requirements. Recognizing that this information is verified elsewhere, CMS is no longer requiring that organ recovery teams conduct a blood type and other final data verification process before organ recovery.

Critical Access Hospitals. CAHs may now provide diagnostic, therapeutic, laboratory, radiology, and emergency services under arrangement and are no longer limited to services provided directly by hospital staff. The condition also clarifies that surgical services are an optional service for a CAH.

As can be seen from the above, this Bulletin could have been much more detailed; however, our purpose was to give you the highlights so that you can work with your hospital leadership, legal counsel, and others to review each revised standard carefully and to determine what changes, if any, need to be made to your hospital policies and medical staff governing documents.

The final rule, with commentary and revisions, is available is at 77 F.R. 29033. Note that the commentary is in the first forty (40) pages (29034-29073); the actual standards can be found in the last three (3) pages (29074-29076).

Authors