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CMS DELAYS INTERPRETATIVE GUIDELINES ON HOSPITAL CONDITIONS OF PARTICIPATION

On May 10, 2012, the Centers for Medicare & Medicaid Services ("CMS") published a Final Rule "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation" ("Final Rule"), which modifies and revises the federal Medicare Conditions of Participation ("CoPs") for hospitals and critical access hospitals ("CAHs"). The Final Rule was designed to reduce the regulatory burden on hospitals and CAHs by "modifying, removing, or streamlining current regulations that [CMS has] identified as excessively burdensome" and is expected to initially save hospitals and CAHs approximately $940 million.

As we reported in the June 2012 edition of Jones Walker's Health Care E*Bulletin, the Final Rule made a number of changes to the hospital CoPs, including, without limitation, in the areas of patient's rights, medical staff, nursing services, medical record services, outpatient services, infection control, and governing body, and is effective July 16, 2012. CMS stated that it would develop interpretative guidelines "to assist hospitals, surveyors, and the public in implementing" the Final Rule.

On June 15, 2012, the Director of the Survey and Certification Group of CMS' Office of Clinical Standards and Quality/Survey & Certification Group issued a memorandum to State Survey Agency Directors stating that, while it is in the process of developing interpretative guidelines to assist surveyors in assessing compliance under the revised CoPs, "due to the number and complexity of the revisions" to the revised CoPs, the interpretative guidelines "may not be published for all of the affected requirements by July 16. . ."

In addition, the memorandum states that, until surveyors receive instructions from CMS, they should not attempt to assess a hospital's compliance with, or cite deficiencies related to, CoP 482.12, which requires a hospital to include one or more members of the medical staff on its governing body, since "CMS is presently considering this policy in light of the numerous comments that have been received since publication of the Final Rule." The memorandum also states that surveyors should "not interpret on their own" this requirement, and must not issue citations related to this specific provision. Further, the memorandum notes that the three accreditation organizations with a CMS-approved Medicare hospital accreditation program (the American Osteopathic Association, Det Norske Veritas Healthcare, and The Joint Commission) were being instructed not to revise their accreditation standards related to this aspect of the composition of the governing body until CMS has addressed the issue completely. The memorandum states that "we are carefully reviewing the comments and will reconsider this requirement in future rulemaking."

As noted above, CMS received a number of comments relating to CoP 482.12. For example, in a letter, dated June 5, 2012, to Marilyn Tavenner, CMS Acting Administrator, the American Hospital Association ("AHA") stated that two revisions to the Final Rule (the change requiring a medical staff member to serve on a hospital's governing board, noted above, as well as the provision prohibiting a health system from having a single,

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integrated medical staff serving more than one hospital) represent substantive policy changes which were not included in the notice of proposed rulemaking ("NPRM") and therefore violate the Administrative Procedures Act ("APA").

The AHA noted that many public and private sector hospitals are adversely affected by the new requirement set forth in CoP 482.12, which the AHA characterizes as "unworkable or ill-advised," and that these hospitals, if given the opportunity to comment, could have raised a number of important policy considerations, including, without limitation:

- The impediments for organizations that have boards that are elected, appointed or otherwise selected by the members of the communities they serve, the duly elected officials of those communities or other public sector officials, or the private shareholders who own the company;
- The challenges for organizations whose medical staffs are composed of individuals who are employed by the organization in dealing with the inherent conflicts of interest that would arise from having an employee on the board; and
- The impediments to communication between the board and the medical staff leadership in places where sunshine laws preclude any two members of a board from conversing about hospital business without appropriate public notice and access.

The AHA then concluded that "the governing body requirement for medical staff participation should be rescinded immediately."

Similarly, in a letter, dated June 8, 2012, to Ms. Tavenner, the National Association of Public Hospitals and Health Systems ("NAPH") stated that it was "deeply troubled by the unexpected requirement – added to the Final Rule introductory text of the regulations at 482.12 (governing body standards) – that would mandate the inclusion of a member of the hospital medical staff on the governing body of a hospital." The provision, according to the NAPH, "poses substantial legal issues for public hospitals," and "is in direct conflict with many state and local law requirements for public hospital governing board membership." The NAPH also stated that this provision of the Final Rule violates the APA, and urged CMS "to either rescind this provision because its promulgation violates [the APA's] notice and comment rulemaking requirements…, or, in the alternative, treat this new policy addition as a proposed rule under the process established in section 1871(a)(4) of the Social Security Act for which comment must be sought." The NAPH also noted that "CMS must act with far greater deliberation before advancing any final regulatory policy proposal on this issue."

HITECH Omnibus Rule Expected By The End of Summer

According to *Health Data Management* (Goedert, 6/6), Farzad Mostashari, the National Coordinator for Health Information Technology within the Office of the National Coordinator for Health Information Technology ("ONC"), announced during the keynote address at the Second International Summit on the Future of Health Privacy in Washington, D.C. that the final HIPAA Omnibus Rule is due to be released by the end of the

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summer. The Omnibus Rule would include changes to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules, as well as changes relating to the Genetic Information Non-Discrimination Act. It was received by the Office of Management and Budget on March 24, 2012.

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