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CMS ISSUES RULES FOR REGULATORY REFORM

On October 18, 2011, the Centers for Medicare & Medicaid Services (CMS) issued two proposed rules and one final rule designed to reduce unnecessary, obsolete, or burdensome regulations applicable to hospitals and other health care providers. The rules were developed in response to President Obama's January 18, 2011, Executive Order 13563, "Improving Regulation and Regulatory Review," which directed executive agencies to establish a plan for conducting ongoing retrospective reviews of existing regulations in order to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive, or those that can be modified to be more effective, efficient, flexible, and streamlined. In August 2011, the Department of Health & Human Services (DHHS) released its "Plan for Retrospective Review of Existing Rules" (Plan), which contained reforms, both completed and proposed, that are designed to save millions of dollars annually. One reform described in the Plan is CMS' large-scale retrospective review of the Medicare Conditions of Participation (CoPs), which was performed in order to remove or revise obsolete, unnecessary, or burdensome provisions. The goal of the review, as stated in the Plan, was to identify opportunities to improve patient care and outcomes and reduce system costs by removing obsolete or burdensome requirements.

As noted above, CMS' current regulatory reforms are set forth in two proposed rules and one final rule, all of which are designed to further the goals set forth in both the Executive Order and DHHS' Plan to improve transparency and help providers operate more efficiently by reducing their regulatory burdens. The first proposed rule, "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation," revises certain CoPs for hospitals and critical access hospitals (CAHs), while the second proposed rule, "Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,"(the "Medicare Regulatory Reform rule") addresses regulatory requirements for a broader range of healthcare providers and suppliers who are regulated under Medicare and Medicaid. According to DHHS' press release, dated October 18, 2011, these two proposed rules take into consideration numerous burden reduction recommendations received from hospitals, CAHs, and patient advocates, among others. CMS estimates that the annual savings to hospitals from the proposed revisions to the CoPs could exceed $900 million in the first year, while CMS' Medicare Regulatory Reform rule could save up to $200 million in the first year. CMS' final rule, "Medicare Program; Changes to the Ambulatory Surgical Centers Patient Rights Conditions of Coverage," reduces regulatory burdens for ambulatory surgery centers (ASCs) and is based on a proposed rule CMS issued in April 2010. CMS estimates that this final rule could generate $50 million in savings per year. Taken

together, the regulatory reform initiatives set forth in these three rules would save nearly $1.1 billion across the health care system in the first year, for a total saving of more than $5 billion over five years.

Proposed Rule – Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation.

As previously stated, CMS has proposed revisions to the Medicare CoPs for hospitals and CAHs. The Medicare CoPs are federal health and safety requirements that hospitals and CAHs must meet in order to participate in the Medicare and Medicaid programs. The proposed revisions are to certain existing CoPs that CMS believes could be reformed, simplified, or eliminated in order to reduce unnecessary burden and costs placed on hospitals and CAHs. The proposed rule would revise a number of CoPs, including, but not limited to, the following:

- *Governing Body* (482.12): Multi-hospital systems (i.e., those that have more than one CMS Certification Number) would be permitted to have one governing body to oversee the multiple hospitals in a single health system.
- *Patient Rights* (482.13): Reporting requirements for hospitals would be modified when the circumstances of a patient's death involve only the use of soft, two-point wrist restraints and seclusion was not involved.
- *Medical Staff* (482.22): Hospitals would be able to grant privileges to both physicians and non-physicians to practice within their scope of practice under state law regardless of whether they are also appointed to the medical staff of the hospital.
- *Nursing Services* (482.23): Hospitals would be permitted to have a single, interdisciplinary care plan that supports coordination of care instead of requiring a separate stand-alone nursing care plans. In addition, patients or their caregivers or support persons would be able to administer certain medications.
- *Infection Control* (483.42): Hospitals would be given flexibility in their approach to the tracking and surveillance of infections.
- *Outpatient Services* (482.54): Hospitals would be given the flexibility to determine the best way to oversee and manage outpatient services by removing the requirement for a single Director of Outpatient Services.

Proposed Rule – Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction.

This proposed Medicare Regulatory Reform rule would make several specific changes to existing Medicare and Medicaid regulations in order to improve transparency, and efficiency, and reduce regulatory burdens. According to CMS, the rule would increase the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care. The proposed changes include the following:

- Eliminating the one year re-enrollment bar after a revocation of Medicare enrollment in certain circumstances where the revocation was related to a failure to respond to a request for information or revalidations.

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- Revising the conditions for coverage for End-Stage Renal Disease (ESRD) to remove unnecessary and duplicative Life Safety Code requirements and specifying which higher-risk ESRD facilities are required to comply with the full federal Life Safety Code requirements.
- Revising the conditions of coverage for ASCs by removing certain emergency response requirements and allowing ASCs flexibility to develop policies and procedures that specify emergency equipment appropriate to the services they provide.
- Eliminating the current Medicare requirement that automatically deactivates a supplier or provider who has not submitted a Medicare claim for 12 consecutive months.
- Replacing time-limited agreements which govern Intermediate Care Facilities for the Mentally Retarded participation in Medicaid with open-ended agreements.
- Removing outdated personnel qualification language for physical therapists and occupational therapists in current Medicaid regulations and instead cross referencing the updated Medicare personnel qualifications.

In addition to the items noted above, the Medicare Regulatory Reform rule also contained additional changes designed to further the goals of removing obsolete or duplicative regulations or of providing clarifying information regarding certain regulations, including removing the mandate that CMS maintain a chart of OMB control numbers; revising the e-prescribing rules for consistency with HIPAA standards; removing certain provisions related to initial determinations, appeals, and reopenings; and removing certain ASC infection control criteria.

Final Rule – Medicare Program; Changes to the Ambulatory Surgical Centers Patient Rights Conditions of Coverage.

In addition to the two proposed rules, CMS also published a final rule that revised the ASC conditions for coverage to allow patient rights information to be provided to the patient, the patient's representative, or the patient's surrogate prior to the start of a surgical procedure, rather than in advance of the date of the procedure. This final rule is based on a proposed rule that CMS issued in April 2010. Prior to the issuance of the final rule, ASCs were generally unable to perform surgeries on the same day that the patient was referred to the ASC for a procedure. This appears to have caused logistical problems and inconveniences for patients who needed ASC services on the same day that they received a physician referral. The final rule no longer requires that the notice of patient rights be provided "in advance of the date of the procedures." Rather, the final rule now requires the notice to be provided "prior to the start of the procedure."

All together, the two proposed rules and one final rule represent CMS' current effort to fulfill the mandate of Executive Order 13563 and help achieve the key goals of the regulatory reform initiative.

—*Lynn M. Barrett*

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REMINDER: JONES WALKER PRESENTS FLORIDA HEALTH CARE SEMINAR

Join us on November 17 in Hollywood, Florida, as we present "***Recent Health Care Trends from a Legal and Compliance Perspective***," another popular Jones Walker Health Care Seminar targeted to health care organizations and their key personnel, such as executives, counsel, compliance officers, and auditors. This seminar will comprise six sessions of topics, including legal issues with physician arrangements and other referral sources; readmissions, quality reporting, and payment models; and enforcement trends. We are pleased to announce that due to newly released federal guidance, we are offering a new session on "***Accountable Care Organizations—Key Legal and Operational Issues Under New Federal Guidance***."

Jones Walker attorneys **Lynn M. Barrett**, **David G. Radlauer**, and **Myla R. Reizen** will be presenting. Additional speakers include **Mark Lavine,** Assistant U.S. Attorney for the Southern District of Florida, **Kathy Reep** of the Florida Hospital Association, **Tim Renjilian** of FTI Consulting, and **Elizabeth White** of Shands HealthCare.

For more information, please click here to view the seminar brochure.

Space is limited, so please e-mail Nicole Csintyan or call 504.582.8456 for more information or to register for this program today.

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JONES WALKER CLOSES TRANSACTION WITH WATKINS LUDLAM

Originally announced in August 2011, the merger between Jones Walker and the Mississippi based law firm, Watkins Ludlam Winter & Stennis P.A., was completed effective November 5, 2011. The completion of the merger brings the total number of Jones Walker attorneys to more than 375 and adds offices in Jackson, Gulfport, and Olive Branch, Mississippi.

Jones Walker now has 15 offices in 6 states and the District of Columbia.

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Jones Walker offers a broad range of legal services to health care industry clients, including regulatory compliance, litigation, investigations, operations, and transactional matters. These legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:

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