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HEALTH CARE

June 2012 Vol. 11 healthcare@joneswalker.com

CMS RELEASES FINAL RULES FOR HEALTH CARE PROVIDERS

On May 10, 2012, the Centers for Medicare & Medicaid Services ("CMS") issued two final rules that are designed to reduce unnecessary, obsolete, and/or burdensome regulations on hospitals and health care providers.[1] These final rules were first proposed in October 2011 and 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. According to a CMS press release, dated May 9, 2012, entitled "HHS Finalizes New Rules To Cut Regulations for Hospitals and Health Care Providers, Saving More than $5 Billion," these rules will help achieve a key goal of President Obama's regulatory reform initiative and save nearly $1.1 billion across the health care system in the first year and more than $5 billion over five years.

As noted above, CMS published two final rules. The first rule, "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation," modifies and revises the federal Medicare Conditions of Participation ("CoPs") for hospitals and critical access hospitals ("CAHs") and is expected to save hospitals and CAHs approximately $940 million initially "as hospitals use [the] new flexibility" provided for in the final rule. CMS anticipates that the greatest potential savings will result from changes to the "medical staff" CoP (§482.22), which is anticipated to save hospitals and CAHs $330 million, and the "outpatient services" CoP (§482.54), which is anticipated to save these providers $300 million. CMS notes that the final rule on CoPs (together with the Medicare Regulatory Reform Rule, discussed below) takes into account a number of burden reduction recommendations from hospitals, CAHs, patient advocates, and others.

Certain Provisions in the Final Rule on CoPs

The final rule on CoPs is designed to reduce the regulatory burden on hospitals and CAHs, by "modifying, removing, or streamlining current regulations that [CMS has] identified as excessively burdensome," including, among other things:

- Requiring that the credentials of all eligible candidates, as defined by the governing body, be reviewed by the medical staff for potential appointment to the hospital medical staff and allowing hospitals to have more flexibility to include other practitioners, such as ARNPs, PAs, and pharmacists, as eligible candidates for the medical staff with hospital privileges to practice in the hospital in accordance with

[1] The final rules were published in the *Federal Register* on May 16, 2012.

JONES WALKER

e*bulletin

HEALTH CARE

June 2012 Vol. 11 healthcare@joneswalker.com

State law, who will perform all functions within their scope of practice and who will function under the rules of the medical staff;

- Supporting and encouraging patient-centered care, through such changes such as allowing hospitals to have a program for patient(s) or caregiver(s)/support person(s) to administer certain medications (both those brought from the patient's home and those dispensed by the hospital), subject to certain requirements, and allowing hospitals to use a single interdisciplinary care plan that addresses nursing and other disciplines (removing the requirement of having a stand-alone nursing care plan);

- Allowing hospitals to determine the best ways to oversee and manage outpatients by removing the unnecessary requirement for a single Director of Outpatient Services;

- Increasing flexibility for hospitals by allowing one governing body to oversee multiple hospitals in a single health system; and

- Allowing CAHs to partner with other providers to provide certain services such as diagnostic, therapeutic, laboratory, and emergency services so they can be more efficient, and at the same time, ensure the safe and timely delivery of care to their patients.

This final rule also allows podiatrists to assume a new leadership role within a hospital and be responsible for the organization and conduct of the medical staff. In addition, it eliminates the "obsolete" requirement that hospitals maintain an infection control log, since hospitals "are already required to monitor infections and do so through various surveillance methods including electronic systems."

This final rule also makes certain changes with respect to patient orders. While the rule retains the requirement that all orders, including verbal orders, must be dated, timed and authenticated promptly by the ordering practitioner, or "other practitioner who is responsible for the care of the patient as specified under §482.12(e) [CoP for "Governing body"] and authorized to write orders by hospital policy in accordance with State law," the rule eliminates the requirement that verbal orders must be authenticated within 48 hours. Rather, the rule defers to State law to establish authentication time-frames. In the event State law does not establish such time-frames, the hospital would be allowed to establish its own time-frame for the authentication of orders, including verbal orders. In addition, the final rule allows for the use of pre-printed and electronic standing orders, order sets, and protocols but only if, among other requirements, the orders and protocols are consistent with nationally recognized and evidence-based guidelines, and have been approved by the medical staff, and the hospital's nursing and pharmacy leadership, who must periodically and regularly review them to determine their continuing usefulness and safety.

And while the final rule allows one governing body to oversee multiple hospitals in a single health system, it does not allow hospitals in multi-hospital systems to have a single integrated medical staff structure. In addition, the final rule requires that the hospital's governing body include at least one medical staff member "as a means

JONES WALKER

e*bulletin

HEALTH CARE

June 2012 Vol. 11 healthcare@joneswalker.com

of ensuring communication and coordination between a single governing body and the medical staffs of individual hospitals in the system."

The final rule is effective July 16, 2012. Perhaps as a result of the numerous changes set forth in the final rule, CMS has stated that it will develop interpretative guidelines "to assist hospitals, surveyors, and the public in implementing" the final rule.

Certain Provisions of the Medicare Regulatory Reform Rule

In its second final rule, "Medicare and Medicare Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction," also known as the "Medicare Regulatory Reform Rule" CMS identified regulations that are "unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries," and finalized a rule that it stated will 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 the divert providing high quality patient care." CMS anticipates that this rule will produce savings of more than $200 million in the first year by promoting efficiency. Specifically, CMS estimates one-time savings relating to End Stage Renal Disease facility reforms, which are anticipated to result in savings of $108.7 million, and Ambulatory Surgical Center reforms, which are anticipated to result in savings of $18.5 million. CMS also anticipated recurring savings of $100 million in connection with changes to the revocation of enrollment/billing privileges provisions.

The final Medicare Regulatory Reform Rule, which applies to health care providers and suppliers, including hospitals, ambulatory surgical centers, end-stage renal disease facilities, durable medical equipment suppliers, and a host of other health care providers and suppliers regulated under Medicare and Medicaid, includes more than two dozen finalized regulatory changes including:

- Eliminating the specific list of emergency equipment Ambulatory Surgical Centers ("ASCs") must have in the facility, and allowing facilities, in conjunction with medical staff and their governing bodies, to develop policies and procedures that specify emergency equipment appropriate to the services they provide;
- Requiring only higher risk End Stage Renal Disease ("ESRD") facilities (those located adjacent to high hazardous occupancies) to comply with the full National Fire Protection Agency Life Safety Code requirements;
- Eliminating the "unnecessarily punitive" enrollment bar for providers and suppliers when it is based on the failure of a provider or supplier to not respond timely to revalidation or other requests for information;
- Eliminating obsolete regulations, including outmoded infection control instructions for ASCs; outdated Medicaid personnel qualification standards for physical and occupational therapists; and duplicative requirements for governing bodies of Organ Procurement Organizations;

JONES WALKER

e*bulletin

HEALTH CARE

June 2012 Vol. 11 healthcare@joneswalker.com

- Replacing inflexible time-limited agreements with open-ended agreements for Medicaid-participating Intermediate Care Facilities that serve people with intellectual disabilities. The regulation also implements a recommendation from stakeholders to replace the term "mental retardation" with "intellectual disability," which is the same change that Congress has made to most of the federal law's references to the term; and

- Updating e-prescribing technical requirements so Medicare Prescription Drug Plans meet current standards.

As with the final rule on CoPs, the Medicare Regulatory Reform Rule is also effective July 16, 2012.

In announcing both final rules, Health and Human Services Secretary Kathleen Sebelius stated "We are cutting red tape and improving health care for all Americans. [] Now it will be easier for health care providers to do their jobs and deliver quality care."

We wish to note that this article is meant to provide a high-level summary of certain of the changes contained in the two final rules and does not discuss all of the changes contained therein; nor does this article discuss those CoPs and other regulations that were not included in the final rules.

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JONES WALKER

e*bulletin

HEALTH CARE

June 2012 Vol. 11 healthcare@joneswalker.com

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