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CMS UPDATES GUIDANCE ON HOSPITAL GOVERNING BODY AND MEDICAL STAFF CONDITIONS OF PARTICIPATION (COPS)

On September 15, 2014, CMS updated its interpretive guidelines (Guidance) to address recent amendments to the Governing Body and Medical Staff Conditions of Participation (CoPs) adopted in the final rule, Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (79 Fed. Reg. 27, 106, effective July 11, 2014) (Final Rule).

Governing Body Changes

The Final Rule eliminates the requirement that the governing body of a hospital include a member of the hospital's medical staff and replaces it with a new requirement that the governing body periodically consult directly with the person responsible for the organization and conduct of the hospital's medical staff (the medical staff leader) regarding the quality of medical care provided to the hospital's patients (Consultation Requirement). The hospital's governing body must adopt policies and procedures for such consultations and document that the required consultations have occurred. Documentation may include meeting agendas, lists of attendees, or minutes of the discussion.

CMS explains that the governing body is expected to determine the appropriate frequency of consultations with the medical staff leader based on various factors specific to the hospital, but consultations should occur at least twice during each calendar or fiscal year. Factors to consider in determining the appropriate frequency of such periodic consultations include the scope and complexity of hospital services offered, specific patient populations served by the hospital, and the issues related to patient safety and quality of care that the hospital may periodically identify.

In the case of a multihospital system with a single governing body, the governing body should consult with the medical staff leader of each separately certified hospital to satisfy the Consultation Requirement. If a multihospital system has a unified medical staff, the governing body must consult with the leader of that staff, who is expected to be aware of the concerns/views of members of the medical staff practicing at each hospital within the system. As used throughout the Guidance, "separately certified" means that a hospital has its own Medicare provider agreement and CMS certification number.

Medical Staff Changes

The Final Rule permits the medical staffs of separately certified hospitals that are part of a hospital system to organize as a unified, integrated medical staff. To form a unified medical staff, the hospital's governing body must elect the unified structure, and such structure must be accepted by majority vote of

medical staff members in accordance with the medical staff's bylaws. Governing boards and their medical staffs have considerable leeway in formulating the details of the voting process, provided the rules are consistent with the following parameters:

- The criteria as to which categories of medical staff members have the right to vote on a unified medical staff must be the same as for other amendments to the medical staff's bylaws.
- It cannot be required, as a condition for holding an opt-out vote, that a petition be signed by the same number of voting members required for a successful vote.
- A supermajority requirement is permissible only if generally required to amend the medical staff's bylaws.
- Where a unified medical staff has already been established, an opt-out decision cannot be delegated to that staff's executive committee, even if the executive committee is otherwise delegated authority to amend unified medical staff bylaws.
- If a hospital system does not currently have a unified medical staff, approval solely by a hospital's medical staff executive committee is permissible if consistent with the hospital's medical staff bylaws governing amendments in effect at the time of the vote.
- The rules may establish a minimum interval between votes on a unified medical staff, but CMS cautions that an interval of more than two years between votes is too long.

Hospitals part of hospital systems are expected to put medical staff bylaws in place to address the process for accepting or opting out of medical staff unification even if the hospital does not currently use a unified medical staff.

Because many systems had already interpreted the medical staff CoPs to permit unified medical staffs prior to the Final Rule, CMS views the prior existence of a unified medical staff as evidence of the election of this option by a hospital's governing body. A hospital with a unified medical staff in place prior to July 11, 2014, is not required to hold a vote among the members of its medical staff. The governing body of such a system, however, should formally notify medical staff members with voting privileges of its preference to continue using the unified medical staff and the members' right to vote to opt out of the unified medical staff.

CMS acknowledges that the process of amending bylaws to address the issue of medical staff unification can be a lengthy one and does not set any firm date requirement for completing such process; however, CMS does expect hospitals part of a system that had a unified medical staff as of July 11, 2014, to have at least initiated the process before December 31, 2014.

The Guidance acknowledges that separately certified hospitals using a unified medical staff may present special challenges. CMS expects hospital and medical staff leadership to be able to explain how the organization and function of the unified medical staff addresses the unique circumstances and concerns of each hospital. The unified medical staff has flexibility in establishing its written policies and procedures for addressing these unique concerns, but, at a minimum, they must cover the following:

- Provide a process by which members can raise their unique concerns with the unified medical staff's leadership.
- Document how members are informed of that process.
- Provide a process for referring the concerns and needs raised to the appropriate committee or other group within the unified medical staff for due consideration.
- Document the outcome of the medical staff's review of the concerns raised.

Other Highlights Regarding Unified Hospital Guidance

CMS attempts to clarify that a multicampus hospital with several inpatient campuses that are provider-based, remote locations of the hospital does not qualify as a multihospital system; rather, a multicampus hospital is one certified hospital and may not have separate medical staffs at each campus. A multicampus hospital that is part of a hospital system consisting of multiple, separately certified hospitals, however, may share a unified medical staff with other separately certified hospitals within the system.

CMS also recommends that systems deciding whether to use a single governing body for multiple hospitals consider the impact on the Medicare payment status of the hospitals within the system. For instance, a hospital system that includes certain types of hospitals being paid under a Medicare payment system other than the Hospital Inpatient Prospective Payment System (such as hospitals-within-hospitals or hospital satellites) may jeopardize the Medicare payment status of those excluded hospitals if it owns both the tenant and host hospitals and uses a unified medical staff for both.

DOL ANNOUNCES DELAY OF HOME CARE MINIMUM WAGE ENFORCEMENT

The United States Department of Labor (DOL) recently announced that it is delaying enforcement of its new rule that extends minimum wage and overtime requirements to most home care workers. The DOL has not changed the effective date of the rule (January 1, 2015) but has implemented a six-month period of nonenforcement, ending June 30, 2015. The DOL's policy statement on this nonenforcement period is available in its entirety here.

Home Care Extension of the Fair Labor Standards Act

In October 2013, the DOL issued a final rule that extends the minimum wage and overtime protections in the Fair Labor Standards Act (FLSA) to all direct care workers employed by third parties, such as home care agencies, who provide essential home care assistance to the elderly and people with illnesses, injuries, or disabilities (Home Care Final Rule). Prior to the Home Care Final Rule, federal law allowed exemptions from minimum wage and overtime compensation for work classified as "companionship services" and from overtime compensation for work classified as "live-in domestic services." The final rule no longer permits third-party employers to claim either exemption, even if the employee is jointly employed by the third party and the individual receiving the services. Organized labor advocates estimate that these modifications will affect nearly two million direct care workers, including home health aides, personal care aides, and certified nursing assistants.

Forthcoming Enforcement

While the DOL's six-month period of nonenforcement will end on June 30, 2015, for the following six-month period (July 1, 2015 to December 31, 2015) the DOL will exercise its prosecutorial discretion in deciding whether to bring enforcement actions against employers for violating obligations resulting from the amended regulations. In making these determinations, it will give strong consideration to the employer's efforts to implement the final rule and the state's efforts to bring publicly funded home care programs into compliance. The enforcement delay is in response to requests from advocacy organizations and states with publicly funded home care programs, which require time to make the necessary budgetary, programmatic, and operational adjustments necessary to comply with the FLSA. The DOL will continue to provide technical assistance to regulated entities, particularly state agencies that administer publicly funded home health care programs.

The DOL maintains a web portal with interactive tools, fact sheets, and other materials to help families, employers, and workers understand the new requirements regarding home health care wages.

OIG RELEASES SPECIAL ADVISORY BULLETIN REGARDING PHARMACEUTICAL COPAYMENT COUPONS

The Office of Inspector General (OIG) recently released a Special Advisory Bulletin (Bulletin) regarding copayment coupons offered by pharmaceutical manufacturers that reduce or eliminate the out-of-pocket cost for patients to obtain brand-name drugs. The OIG released the Bulletin to alert pharmaceutical manufacturers that it has found copayment coupons are being used to induce the purchase of items payable under Medicare Part D, thereby exposing pharmaceutical manufacturers to sanctions under the

anti-kickback statute (AKS) and associated federal fraud and abuse laws.

The OIG takes the position that the copayment coupons, including print or electronic coupons, debit cards, and direct reimbursement of copayments, constitute remuneration offered to consumers to induce the purchase of specific brand-name drugs and thereby implicate the AKS. For this reason, pharmaceutical manufacturers generally take steps to prevent the use of copayment coupons by federal program beneficiaries, including, but not limited to, claims processing edits and language on the face of a coupon stating that the coupon may not be used for drugs payable by a federal health care program. The Bulletin alerts pharmaceutical manufacturers that the OIG has determined they are not taking adequate precautions to prevent copayment coupons from being used to purchase drugs paid for by Medicare Part D.

The OIG released the Bulletin in concurrence with a report conducted by the OIG's Office of Evaluation and Inspections (OEI) regarding the measures pharmaceutical manufacturers employ to ensure that their copayment coupons are not used to purchase drugs payable by a federal health care program. The OEI found that certain pharmaceutical manufacturers do not (1) consistently place notices on copayment coupons stating that federal health care program beneficiaries are ineligible to use such coupons or (2) adequately monitor claims submitted in connection with Part D drug purchases when processing copayment coupons. The OEI also stated that Medicare Part D plans have difficulty identifying the use of a copayment coupon for drugs paid for by the Part D system because copayment coupons are not transparent in the pharmacy claims transaction system.

The OIG noted that pharmaceutical manufacturers are responsible for violations of the AKS arising from copayment coupons and warned that failure to take appropriate action to prevent the use of copayment coupons for drugs paid for by federal health care programs could constitute evidence of intent to induce the purchase of items or services in violation of the AKS. Therefore, pharmaceutical manufacturers may consider reviewing their compliance programs and claims review processes to ensure mechanisms are in place to monitor and prevent the improper use of copayment coupons by federal health care program beneficiaries.

Please contact any member of the Health Law Group at Robinson+Cole if you have questions:

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