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ISSUE ALERTS

CMS EASES ASC REGULATIONS CONCERNING PATIENT TRANSFERS, EXAMINATIONS, AND EMERGENCY PREPAREDNESS PLANNING

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In response to an executive order from President Trump admonishing the Department of Health and Human Services ("HHS") to limit regulatory burdens, the Centers for Medicare & Medicaid Services ("CMS") published a final rule that significantly reduces a variety of provider obligations. Notably, the Final Rule ends the requirement that ambulatory surgical centers ("ASCs") enter into written transfer agreements with local hospitals, eliminates regulations requiring ASCs to conduct certain pre-operation patient assessments, and scales back emergency preparedness requirements for ASCs and other providers. The Final Rule is set to become effective on November 29, 2019.

FINAL RULE ENDS HOSPITAL TRANSFER AGREEMENT REQUIREMENT FOR ASCS

HHS regulations currently require ASCs, as part of the Medicare Conditions for Coverage, to either maintain a written transfer agreement with a "Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services" or to ensure that each physician who performs services at the ASC holds admitting privileges at such a hospital. Under the provisions of the Final Rule, ASCs are no longer specifically required to maintain a formal hospital transfer agreement or to ensure that their physicians maintain admitting privileges at any specific hospital. In lieu of the written transfer agreement requirement, the Final Rule generally requires ASCs to maintain an effective procedure for transfers of patients requiring emergency hospital care.

CMS believes that the change to the hospital transfer agreement requirements is appropriate due to "the small burden of transfers" and "the burden ASCs incur when faced with local hospital competition issues." CMS noted that, under the new regulations, ASCs will not be "precluded from obtaining hospital transfer agreements or hospital physician admitting privileges when possible," but CMS believes that such agreements with hospitals should not be

expressly required for an ASC to participate in the Medicare and Medicaid programs. CMS stressed the importance of communication between ASCs and hospitals concerning potential patient transfers, and accordingly, it will require ASCs to periodically provide written notice of their operations and patient population to the local hospital.

CMS CHANGES PRE-SURGERY MEDICAL HISTORY AND PHYSICAL ASSESSMENT REQUIREMENTS FOR ASC PROCEDURES

Current regulations require a physician or other practitioner to perform a comprehensive history and physical ("H&P") examination on each patient within the thirty-day period preceding the date of the scheduled surgery and a physical assessment upon admission that includes, at minimum, an examination for changes in a patient's conditions since the last documented H&P. The Final Rule, however, eliminates the thirty-day H&P examination mandate and instead implements new regulations that will require ASCs to institute their own policies to determine which patients will require H&P examinations prior to surgery.

CMS describes this revision as a move to "defer, to a certain extent, to the ASC policy and operating physician's clinical judgment to ensure that patients receive the appropriate pre-surgical assessments tailored to the patient and the type of surgery being performed." CMS firmly rejected a "one size fits all" approach to H&P examinations, stating that variations between ASCs are not necessarily undesirable and would allow each ASC to "take into account unique patient characteristics."

CMS will still require that the physician performing the procedure document medical conditions and test results in the patient's medical record "before, during and after surgery" and that all pre-surgical assessments feature documentation of drug and biologic allergies." CMS advised that ASCs should choose "the content of ASC-wide policies surrounding the appropriate use of medical histories and physicals, as well as pre-operative testing" based on "specialty societies, medical literature, past experience, or other factors."

FINAL RULE LOOSENS EMERGENCY PREPAREDNESS REQUIREMENTS

The Final Rule also eases HHS's emergency planning requirements for most facilities, including ASCs. Under the new regulations, facilities are required to review their emergency preparedness plan and provide emergency training to their employees every two years, rather than annually. The Final Rule also ends the requirement that facilities document efforts to contact applicable tribal, regional, state, or federal emergency planning officials as part of their preparedness plans.

Please note, however, that facilities are still obligated to update their emergency preparedness plans and train employees whenever reasonably necessary to ensure that the plans remain effective, even if such updates and training must be undertaken more frequently than every two years. Furthermore, while facilities will no longer be expressly required to document communications with local officials, they must still coordinate with local officials as necessary concerning their emergency preparedness planning.

TAKEAWAYS

The Final Rule eases CMS regulatory compliance burdens on ASCs, enabling them to operate more independently and efficiently. Despite these changes, there may be reasons from a licensing, risk management, or operations perspective to continue with current practices regarding transfer agreements, H&Ps, and emergency preparedness. The full text of the Final Rule can be found **here**.

FOR MORE INFORMATION

If you have questions or want more information regarding the Final Rule, contact your legal counsel. If you do not have regular counsel for such matters, Foulston Siefkin LLP would welcome the opportunity to work with you to

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