

Alert | Health Care & FDA Practice



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CMS Releases Burden Reduction Final Rule

On Sept. 25, 2019, the Centers for Medicare and Medicaid Services (CMS) issued a final rule aimed at reducing burden on health care providers and suppliers, while continuing to emphasize patient health and safety. In drafting the final rule, CMS worked to identify obsolete regulations that could be reformed or eliminated altogether, as well as noncodified rules that could be streamlined, with a specific focus on freeing up resources that providers, plans, and states could utilize to improve patient outcomes.

The rule finalizes changes to current CMS requirements, Conditions of Participation (CoPs), and Coverage/Conditions for Certification (CfCs), with the goal of simplifying current regulations and increasing provider flexibility, while also allowing providers more time to focus on patient care. The rule affects a wide scope of providers, including hospitals, critical access hospitals (CAHs), rural health centers, federally qualified health centers (FQHCs), ambulatory surgical centers (ASCs), transplant centers, home health agencies (HHAs), hospices, comprehensive outpatient rehabilitation facilities, community mental health centers, and religious nonmedical health care institutions (RNHCIs). CMS anticipates a total first year net savings of approximately \$843 million, and slightly more in future years.

CMS made few significant changes from the burden reduction proposed rule. These changes include CMS' proposal to remove the requirement at 42 C.F.R. § 484.110(e) that HHAs provide a copy of the clinical record to a patient, upon request, by the next home visit, while retaining the requirement that the requested clinical record copy be provided within four business days. However, in response to commenters' responses that this did not sufficiently remove regulatory burdens, CMS did not make changes to § 484.110(e) in this final rule.

The final rule addresses a broad range of issues impacting providers, with many changes focusing on reducing the frequency of certain required activities, revising timelines for certain requirements, and

removing duplicative or unnecessary requirements. CMS finalizes roughly 30 major revisions through the issuance of this rule. Some key provisions include:

- Removing an ASC requirement mandating that a patient undergo a medical history and physical examination within 30 days of a procedure, and replacing with requirements that increase provider flexibility and generally defer to the ASC policy and operating physician's clinical judgment;
- Providing hospitals with the option to establish a medical staff policy describing the circumstances under which the hospital can utilize a presurgery/preprocedure assessment for an outpatient, instead of the previously required comprehensive medical history and physical examination;
- Revising the requirement that Rural Health Clinic (RHC) and FQHC patient care policies be reviewed at least annually by a group of professional personnel, to be reviewed every other year in order to reduce the frequency of policy reviews;
- Changing HHA rules by removing requirements for verbal notification of all patient rights, and replacing with a requirement that verbal notice must be provided for rights related to payments made by Medicare, Medicaid, and other federally funded programs, and potential patient financial liabilities as specified in the Social Security Act; and
- Updating home health aide requirements by allowing skill competencies to be assessed by observing an aide performing the skill with either a patient or a pseudo-patient as part of a simulation, and revising a previous requirement that an aide found to be deficient must complete a full competency evaluation. An aide would only be required to complete retraining and a competency evaluation directly related to the deficient skills.

The final rule was published in the Federal Register on Monday, Sept. 30, 2019 and is effective on Nov. 29, 2019.

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