Issue Brief

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CMS Issues Final Rule Regarding Regulatory Burden Reductions

The Centers for Medicare & Medicaid Services issued a final rule regarding "Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility and Improvement in Patient Care."

"This final rule reforms Medicare regulations that are identified as unnecessary, obsolete or excessively burdensome on health care providers and suppliers. Additionally, this rule updates fire safety standards for Medicare- and Medicaid-participating end-stage renal disease facilities by adopting the 2012 edition of the Life Safety Code and the 2012 edition of the Health Care Facilities Code. Finally, this final rule updates the requirements that hospitals and critical access hospitals must meet to participate in the Medicare and Medicaid programs."

The final rule is effective 60 days after publication. Publication of the 393-page rule is scheduled for Monday, Sept. 30. A copy of the document currently is available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-20736.pdf.

COMMENT

The changes to the regulations account for 25 percent of the rule, some 88 pages.

MAJOR PROVISIONS ARE AS FOLLOWS.

CMS is finalizing the following revisions.

a. Discharge Planning in Religious Nonmedical Health Care Institutions
CMS revised the requirements at 42 CFR 403.736(a) and (b) pertaining to a discharge plan. These facilities will no longer have to prepare discharge instructions when a patient moves to a medical facility. RNHCIs only will have to provide discharge instructions to the patient and/or the patient's caregiver when the patient is discharged home.

b. Ambulatory Surgical Center: Transfer Agreements with Hospitals
CMS is replacing the requirement at § 416.41(b)(3) that ASCs have written transfer agreements or privileges with the local hospital with a requirement that ASCs must periodically provide the local hospital with written notice of its operation and patient population served. All ASCs must continue to have an effective procedure for immediate transfers to a hospital for patients

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requiring emergency medical care beyond the capabilities of the ASC.

c. ASC Requirements for Comprehensive Medical History and Physical Assessment
CMS is removing the current requirements at § 416.52(a) for a history and physical within 30 days of the procedure, and replacing them with requirements that defer, to a certain extent, to the ASC policy and operating physician's clinical judgment to ensure that patients receive the appropriate presurgical assessments tailored to the patient and the type of surgery being performed. CMS still will require the operating physician to document any preexisting medical conditions and appropriate test results in the medical record before, during and after surgery. In addition, CMS has retained the requirement that all presurgical assessments include documentation regarding any allergies to drugs and biologicals, and that the medical H&P, if completed, be placed in the patient's medical record before the surgical procedure.

d. Hospice Requirements for Medication Management
CMS is removing the procedural requirements at § 418.106(a)(1) related to having an individual with specialty knowledge of hospice medications on the hospice staff.

e. Hospice Requirements: Orientation of Skilled Nursing Facility and Intermediate Care Facilities for Individuals with Intellectual Disabilities Staff
For hospices that provide hospice care to residents of a skilled nursing facility or intermediate care facilities for individuals with intellectual disabilities, CMS is requiring hospices to work with their chosen SNF and ICF partners to educate facility staff about the hospice philosophy of care and specific hospice practices. CMS believes this will encourage collaboration between both entities and will avoid duplication of efforts with other hospices that are orienting the same facility staff.

f. Hospital Quality Assessment and Performance Improvement Program
CMS is finalizing a new standard at 42 CFR 482.21(f), "unified and integrated QAPI program for multihospital systems." For a hospital that is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals if the arrangement is in accordance with all applicable state and local laws.

g. Hospital Requirements for Comprehensive Medical History and Physical Examinations
(§§ 482.22, 482.24 and 482.51)
CMS is allowing hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals can utilize a presurgery/preprocedure assessment for an outpatient, instead of a comprehensive medical H&P examination.

h. Hospital Infection Control Program
CMS is broadly revising §482.42 and issuing a new standard at § 482.42(d), "unified and integrated infection prevention and control and antibiotic stewardship programs for multihospital systems." Like the requirement for a unified and integrated QAPI program, the standard for infection control permits a hospital that is part of a hospital system consisting of multiple separately certified hospitals using a single governing body, such body can

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elect to have a unified and integrated infection prevention and control program for all of its member hospitals in accordance with all applicable state and local laws.

i. Special Requirements for Psychiatric Hospitals
At § 482.61(d), CMS is clarifying the scope of authority for nonphysician practitioners, or doctors of medicine and doctors of osteopathic medicine, to document progress notes of patients receiving services in psychiatric hospitals.

j. Special Requirement for Transplant Centers and Definitions
CMS is making a nomenclature change at 42 CFR part 482, and the transplant center regulations at §§ 482.68, 482.70, 482.72 through 482.104, and at § 488.61. This change updates the terminology used in the regulations to conform to the terminology that is widely used and understood within the transplant community, thereby reducing provider confusion.

k. Data Submission, Clinical Experience and Outcome Requirements for Reapproval of Transplant Centers
CMS is removing the requirements at § 482.82 that state that transplant centers must meet all data submission, clinical experience and outcome requirements in order to obtain Medicare reapproval.

l. Special Procedures for Approval and Reapproval of Organ Transplant Centers
CMS is revising § 488.61(f) through (h) to remove the requirements with respect to the reapproval process for transplant centers. CMS is retaining the requirements in § 488.61(f) through (h) that pertain to the initial approval process for transplant centers.

m. Home Health Agency Requirements for Verbal Notification of Patient Rights and Responsibilities
CMS is removing the requirements for verbal (meaning spoken) notification of all patient rights at § 484.50(a)(3) and replacing it with a requirement that verbal notice must be provided for those 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.

n. Personnel Requirements for Portable X-Ray Technologists
CMS is revising § 486.104(a), "condition for coverage: qualifications, orientation and health of technical personnel," to focus on the qualifications of the individual performing services.

o. Portable X-Ray Requirements for Orders
CMS is revising the requirements for portable X-ray orders at § 486.106(a)(2) by removing the requirement that physician or nonphysician practitioners' orders for portable X-ray services must be written and signed, and replacing the specific requirements related to the content of each portable X-ray order with a cross-reference to the requirements at 42 CFR 410.32, which also apply to portable X-ray services.

p. Emergency Preparedness Requirements: Requirements for Emergency Plans
CMS is removing the requirements from its emergency preparedness rules for Medicare and Medicaid providers and suppliers that facilities document efforts to contact local, tribal, regional, state and federal emergency preparedness officials, and that facilities document their participation in collaborative and cooperative planning efforts.

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q. Emergency Preparedness Requirements: Requirements for Annual Review of Emergency Program
CMS is revising this requirement so that applicable providers and suppliers review their emergency program biennially, except for long-term care facilities, which will still be required to review their emergency program annually.

r. Emergency Preparedness Requirements: Requirements for Training
CMS is revising the requirement that facilities develop and maintain a training program based on the facility's emergency plan annually by requiring facilities to provide training biennially (every two years) after facilities conduct initial training for their emergency program, except for long-term care facilities, which will still be required to provide training annually. In addition, CMS is requiring additional training when the emergency plan is significantly updated.

s. Emergency Preparedness Requirements: Requirements for Testing
For inpatient providers, CMS is expanding the types of acceptable testing exercises that may be conducted. For outpatient providers, CMS is revising the requirement such that only one testing exercise is required annually, which may either be one community-based full-scale exercise, if available, or an individual facility-based functional exercise every other year and in the opposite years. These providers may choose the testing exercise of their choice.

Proposals that Reduce the Frequency of Activities and Revise Timelines

a. Comprehensive Outpatient Rehabilitation Facility Utilization Review Plans
CMS is amending the utilization review plan requirements at § 485.66 to reduce the frequency of utilization reviews from quarterly to annually.

b. CAH Annual Review of Policies and Procedures
CMS is changing the requirement at § 485.635(a)(4) to require a CAH's professional personnel to, at a minimum, conduct a biennial review of its policies and procedures instead of an annual review.

c. Community Mental Health Center Requirements for Updating the Client Assessment
At § 485.914, CMS is removing the requirement that all CMHC clients receive an updated assessment every 30 days. Instead, CMS would require updates of the patient assessment in accordance with client needs and standards of practice. For clients receiving partial hospitalization services, CMS is retaining the 30-day assessment update timeframe to be consistent with existing Medicare payment requirements for recertification of partial hospitalization services.

d. Rural Health Clinic and Federally Qualified Health Center Review of Patient Care Policies
CMS is revising the requirement at § 491.9(b)(4) that RHC and FQHC patient care policies be reviewed at least annually by a group of professional personnel, to review every other year to reduce the frequency of policy reviews.

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e. RHC and FQHC Program Evaluation
CMS is revising the requirement at § 491.11(a) by changing the frequency of the required RHC or FQHC evaluation from annually to every other year.

Proposals That Are Obsolete, Duplicative or that Contain Unnecessary Requirements

a. Hospice Aide Training and Competency Requirements
CMS is revising § 418.76(a)(1)(iv) to remove the requirement that a state licensure program meet the specific training and competency requirements set forth in § 418.76(b) and (c) in order for such licensure to qualify a hospice aide to work at a Medicare-participating hospice, deferring to state licensure requirements.

b. Medical Staff: Autopsies
CMS is finalizing its proposal to remove the requirement for hospitals at § 482.22(d), which states that a hospital's medical staff should attempt to secure autopsies in all cases of unusual deaths, and of medical-legal and educational interest. CMS is deferring to state law regarding such medical-legal requirements.

c. Hospital and CAH Swing-bed Requirements
CMS is removing the cross reference to § 483.10(f)(9) at § 482.58(b)(1) (for hospital swing-bed providers) and § 485.645(d)(1) (for CAH swing-bed providers); the repealed provisions gave a resident the right to choose to, or refuse to, perform services for the facility if they so choose.

CMS is removing the cross-reference to § 483.24(c) at § 482.58(b)(4) (for hospital swing-bed providers) and § 485.645(d)(4) (for CAH swing-bed providers) requiring that the facility provide an ongoing activity program based on the resident's comprehensive assessment and care plan directed by a type of qualified professional specified in the regulation.

CMS is removing the cross-reference to § 483.70(p) at § 482.58(b)(5) (for hospital swing-bed providers) and § 485.645(d)(5) (for CAH swing-bed providers) requiring facilities with more than 120 beds to employ a social worker on full-time basis.

CMS is removing the cross-reference to § 483.55(a)(1) at § 482.58(b)(8) (for hospital swing-bed providers) and § 485.645(d)(8) (for CAH swing-bed providers) requiring that the facility assist residents in obtaining routine and 24-hour emergency dental care.

d. Home Health Agency Home Health Aide Requirements
CMS is revising § 484.80(c)(1) to clarify that skill competencies may be assessed by observing an aide performing the skill with either a patient or a pseudo-patient as part of a simulation. We are defining the terms "pseudo-patient" and "simulation" in § 484.2.

e. CAH Disclosure Requirements
CMS is removing § 485.627(b)(1), the requirement for CAHs to disclose the names of people with a financial interest in the CAH. This currently is a requirement under the program integrity requirements at 42 CFR 420.206, which are referenced in the provider agreement rules in 42 CFR 489.53(a)(8), making this CAH Conditions of Participation requirement duplicative of those regulations.

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Summary of Costs and Benefits for Regulatory Provisions to Promote Efficiency, Transparency and Burden Reduction

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

1. Overall Impact

This final rule says it will create savings and reduce burden in many areas. Several of the changes will create measurable monetary savings for providers and suppliers, while others will create less quantifiable savings of time and administrative burden. CMS says it anticipates a total first year net savings of approximately $843 million for providers, and slightly more in future years.