

President

Donald A. Molony, MD
Houston TX

November 19, 2018

President-Elect

Ralph Atkinson III, MD
Nashville, TN

Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

ATTN: CMS-3346-P

PO Box 8010

Baltimore, MD 21244-1810

Secretary

Chris Brown
Cranbury, NJ

Treasurer

Stephanie Hutchison, MBA
Seattle, WA

Re: CMS-3346-P: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Past-President

John Wagner, MD, MBA
Brooklyn, NY

Dear Ms. Verma,

EDAC Chair

Susan Caponi, MBA, RN, BSN
Lake Success, NY

The Forum of ESRD Networks appreciates the opportunity to comment on the proposed rule CMS-3346-P. We will be limiting our comments to those sections of the proposed rule that specifically relate to the renal services: Requirements for Medical History and Physical Assessment, Emergency Preparedness Requirements and Transplant Centers. Below are our comments.

MAC Chair

David Henner, DO
Pittsfield, MA

KPAC Chair

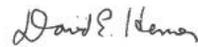
Derek Forfang
San Pablo, CA

Thank you for your consideration,



Donald A. Molony, MD

President, Forum of ESRD Networks



David Henner, DO

Chair, Forum Medical Advisory Council

EDAC Vice-Chair

Brandy Vinson
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KPAC Vice-Chair

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Dee LeDuc
Birchwood, WI

c. ASC Requirements for Comprehensive Medical History and Physical Assessment

We propose to remove the current requirements at § 416.52(a) and replace 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 pre-surgical assessments tailored to the patient and the type of surgery being performed. We still would require the operating physician to document any pre-existing medical conditions and appropriate test results, in the medical record, which would have to be considered before, during and after surgery. In addition, we have retained the requirement that all pre-surgical assessments include documentation regarding any allergies to drugs and biologicals, and that the medical history and physical examination (H&P), if completed, be placed in the patient’s medical record prior to the surgical procedure.

Forum Recommendation: We support this proposal to defer to the physician’s clinical judgment to ensure patients receive appropriate pre-surgical assessments tailored to the patient and the type of surgery being performed, rather than require comprehensive H&P for all ASC surgeries.

g. Hospital Requirements for Comprehensive Medical History and Physical Examinations (§§ 482.22, 482.24, and 482.51)

We propose to allow hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals could utilize a pre-surgery/pre-procedure assessment for an outpatient, instead of a comprehensive medical history and physical examination (H&P). We believe that the burden on the hospital, the practitioner, and the patient could be greatly reduced by allowing this option. In order to exercise this option, a hospital would need to document the assessment in a patient’s medical record. The hospital’s policy would have to consider patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure; nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and applicable state and local health and safety laws.

Forum Recommendation: We support this proposal to allow hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals could utilize a pre-surgery/pre-procedure assessment for an outpatient, instead of a comprehensive medical history and physical examination (H&P).

p. Emergency Preparedness Requirements: Requirements for Emergency Plans

We propose to eliminate part of the requirement from § 482.15(a)(4) for hospitals and other parallel provisions for other affected Medicare and Medicaid providers and suppliers (referred to collectively as “facilities,” throughout the remainder of this proposed rule where applicable), 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. In accordance with the remaining requirement at §482.15(a)(4), facilities would still be required to include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials’ efforts to maintain an integrated response during a disaster or emergency situation. Only the documentation requirements would be eliminated.

Forum Recommendation: We support the proposal to eliminate the requirement for facilities to document their efforts to contact local, tribal, regional, State, and Federal emergency

preparedness officials, and for facilities to document their participation in collaborative and cooperative planning efforts. We agree that there still needs to be a process for cooperation and collaboration with these entities, while eliminating the documentation requirements

g. Emergency Preparedness Requirements: Requirements for Annual Review of Emergency Program

On September 16, 2016, we finalized a rule imposing emergency preparedness requirements on most Medicare and Medicaid facilities (Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 FR 63860). Facilities participating in Medicare and/or Medicaid are now required, among other things, to review their emergency preparedness programs annually. This includes a review of their emergency plans, policies and procedures, communication plans, and training and testing programs. We propose to revise these requirements, so that applicable providers and suppliers have increased flexibility with compliance.

Forum Recommendation: We support the proposal to eliminate the requirement for facilities to review their emergency preparedness programs annually, and agree with allowing facilities increased flexibility in the timing of their program reviews.

h. Emergency Preparedness Requirements: Requirements for Training

As with the review of the emergency plan previously discussed, we propose to revise the requirement that facilities develop and maintain a training program based on the facility's emergency plan annually. Instead, we would require that facilities provide training biennially (every 2 years) after facilities conduct initial training for their emergency program. In addition, we propose to require additional training when the emergency plan is significantly updated.

Forum Recommendation: We support the proposal to replace the requirement for annual training of facilities' emergency plan with biannual training, and when the plan is significantly updated.

i. Emergency Preparedness Requirements: Requirements for Testing

For inpatient providers, we propose to expand the types of acceptable testing exercises that may be conducted such that one of the two annually required testing exercises may be an exercise of their choice, which may include one community-based full-scale exercise, if available, an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator. For outpatient providers, we propose to revise the requirement such that only one testing exercise is required annually, which may be either 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 chose the testing exercise of their choice which may include a community-based full-scale exercise, if available, a facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

Forum Recommendation: We support the proposal to expand the types of acceptable testing exercises for facilities to testing exercises of their choice. However, we do believe facilities should be encouraged to conduct full-scale exercises on occasion, in collaboration with community to better test and improve their emergency response plan if needed.

E. Transplant Centers

1. Special Requirement for Transplant Centers (§§ 482.68 and 482.70)

Section 482.68 generally describes the requirements that a transplant center must meet in order to participate in the Medicare program; section § 482.70 sets out definitions of terms used in the regulations. Specifically, in addition to meeting all the CoPs as a hospital, a transplant center must meet the CoPs specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

2. Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers

We propose to remove the requirements at § 482.82 that require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. Transplant centers will still be required to comply with the CoPs at §§ 482.72 through 482.104 and the data submission, clinical experience, and outcome requirements for initial Medicare approval under § 482.80.

3. Special Procedures for Approval and Re-Approval of Organ Transplant Centers

Section 488.61 describes the survey, certification, and enforcement procedures for transplant centers, including the periodic review of compliance and approval as set out at § 488.20. Section 488.61(f) through (h) set out the process for our consideration of a transplant center's mitigating factors in initial approval and re-approval surveys, certifications, and enforcement actions for transplant centers. The provisions also set out definitions and rules for transplant systems improvement agreements. We propose to remove the requirements at § 488.61(f) through (h) with respect to the re-approval process for transplant centers. This change corresponds to the proposed removal of the provisions § 482.82, described previously.

Forum Recommendations: We support the proposed changes as written. These changes should result in a significant reduction in the administrative burden on transplantation centers through a reduction in the duplication of efforts directed towards monitoring quality and safety. These changes may encourage transplant centers to accept patients with a higher risk profile but who are otherwise good candidates for receiving a kidney transplantation. We would encourage continuing analysis to determine if one of the intended outcomes, namely, making transplantation more available to a greater proportion of the ESRD population and increasing the number of successful kidney transplants, results from these changes.

The Forum would request further clarification from CMS regarding CMS's intent to "...continue to monitor and assess outcomes, after initial Medicare approval, through the transplant and hospital QAPI programs." Specifically, does this language imply additional reporting requirements on the part of hospital-based and transplant center-based QAPI programs to CMS? If not, does CMS anticipate monitoring hospital and/or transplant based QAPI programs through a different mechanism?

The Forum would support the requirement that transplant programs should continue to focus on maintaining high standards that protect patient health and safety and produce positive outcomes for transplant recipients. Therefore, we would support continuing to monitor and assess outcomes, after initial Medicare approval, through the transplant and hospital QAPI programs."