Department of Health & Human Services Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



# Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-18-ESRD REVISED: 03.07.2017

**DATE:** January 13, 2017

**TO:** State Survey Agency Directors

**FROM:** Director

Survey and Certification Group

**SUBJECT:** Delayed Implementation of End Stage Renal Disease (ESRD) Interim Final Rule

with Comment (IFC) – Third Party Payment

\*\*\* Reminder for State Agencies and Regional Offices \*\*\*

## **Memorandum Summary**

- On December 14, 2016, an IFC concerning third party payment requirements for dialysis facilities was published in the Federal Register (81 Fed. Reg. 90211). An interim surveyor worksheet was then released to assist surveyors in evaluating compliance with the requirements of the IFC during ESRD surveys pending issuance of interpretive guidance.
- **Delayed Implementation Date:** Pursuant to a Temporary Restraining Order (TRO) issued on January 12, 2017 temporarily enjoining implementation of the IFC pending further order of the court, use of the interim surveyor worksheet (as directed by S&C: 17-16-ESRD) and enforcement of the provisions in the IFC (amending 42 C.F.R. §§ 494.70 and 494.180) in ESRD surveys will cease until further notice.
- State Survey Agency (SA) Directors are requested to immediately reach out to all ESRD surveyors confirming their knowledge of and understanding of the delayed implementation of the interim surveyor worksheet (as directed by policy memorandum S&C: 17-16-ESRD) until further notice.

### **Background**

On December 14, 2016, an IFC concerning third party payment and ESRD facilities was published in the Federal Register (see <a href="https://www.gpo.gov/fdsys/pkg/FR-2016-12-14/pdf/2016-30016.pdf">https://www.gpo.gov/fdsys/pkg/FR-2016-12-14/pdf/2016-30016.pdf</a>). This rule affects ESRD suppliers that make payments of premiums for individual market health plans (in any amount) whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments). These Conditions for Coverage (CfC) are 42 C.F.R. § 494.70 Patient Rights (c) Standard: Right to be informed of health insurance options and 42 C.F.R. § 494.180

Governance (k) Standard: Disclosure of financial assistance to insurers. These requirements are intended to ensure insurance coverage decisions are made openly and transparently with full, accurate information, and that the information provided is not affected by the financial interest of the dialysis facility.

We are reminding SAs to cease, pursuant to a temporary restraining order, use of the interim surveyor worksheet included within previous instructions (S&C: 17-16-ESRD) regarding Third Part Payment in ESRD. This policy memorandum is to confirm with all SA Directors that this instruction remains in place and accordingly ESRD surveyors may not utilize the worksheet, Evaluation of Third Party Payment Requirements, which was provided in the memorandum S&C: 17-16-ESRD.

#### **Immediate Action**

SA Directors are requested to immediately reach out to all ESRD surveyors in the State and confirm their knowledge of and their understanding of the restriction on the use of this worksheet and discussions regarding third party payment during the ESRD survey.

### **Discussion**

The ESRD IFC included a scheduled implementation date 30 days after publication in the Federal Register with the exception of one section, 42 C.F.R. § 494.180(k), which has a delayed implementation date effective July 1, 2017 if there is a potential for a coverage gap for the beneficiary.

#### **Immediate Action**

On January 12, 2017, a United States District Court in the Eastern District of Texas, Sherman Division (Civil Action No. 4:17-CV-16), granted an Emergency Motion for a TRO to temporarily enjoin implementation and enforcement of the IFC pending further order of the court.

Surveyors should immediately cease incorporation of the surveyor questionnaire tool (contained in S&C: 17-16-ESRD) into the ESRD survey process until further notice.

**Contact:** Please email any questions to the ESRD mailbox at <u>ESRDQuestions@cms.hhs.gov</u>.

**Effective Date:** Immediately. This information should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators as soon as possible.

/s/ David R. Wright

cc: Survey and Certification Regional Office Management